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Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

FIG. 1

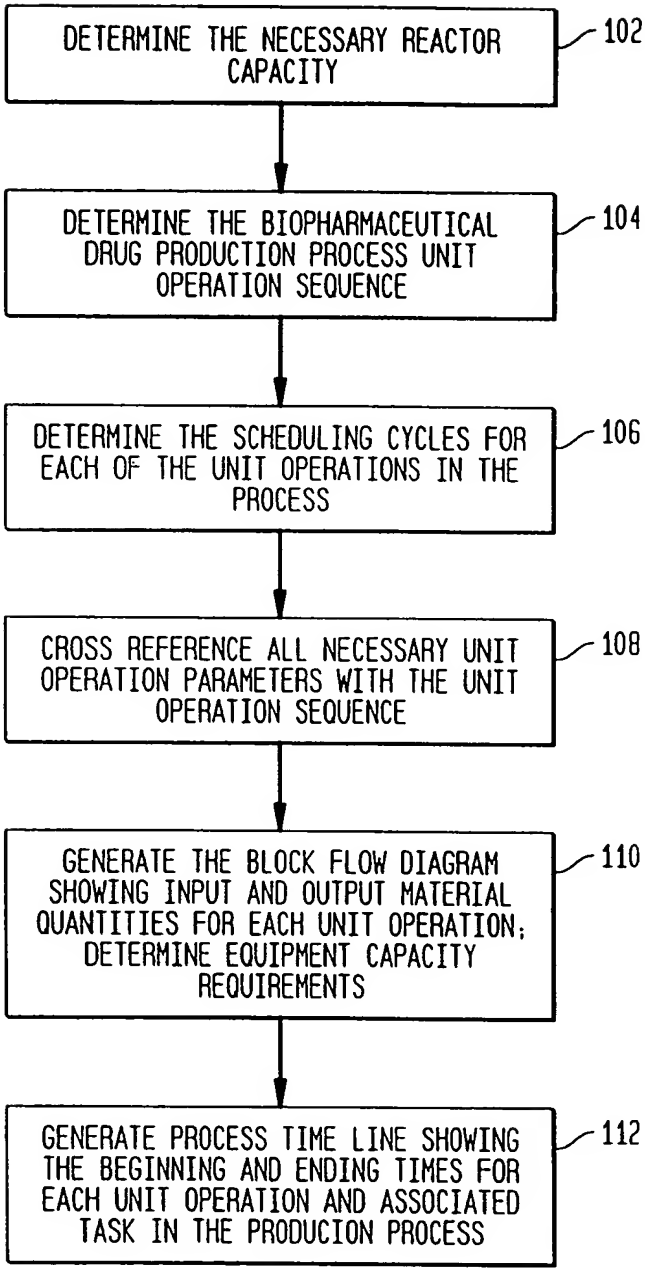

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FIG. 2

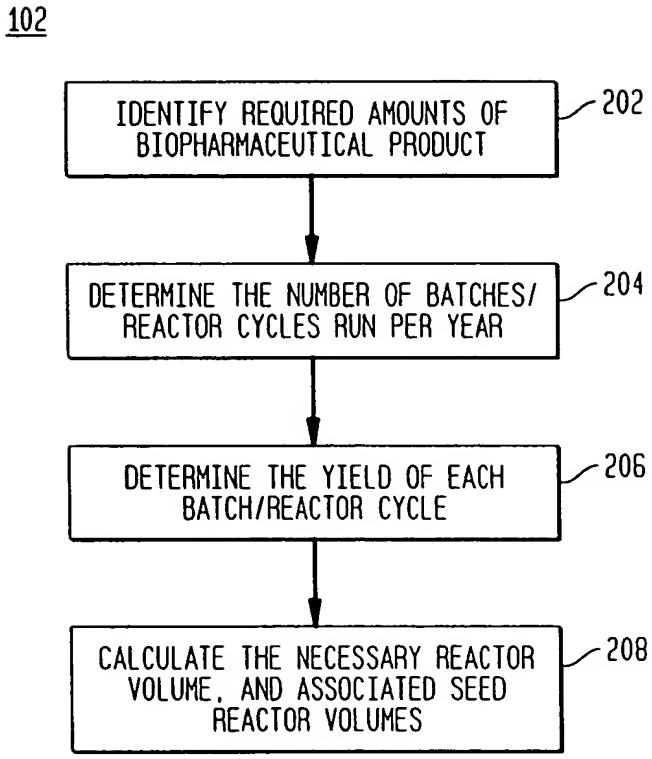

FIG. 3
UNIT OPERATIONS LIST

MICROBIAL FERMENTATION PROCESS

UOP SEQ. NO.	CODE	UNIT OPERATION TYPE	CYCLES PER									RECOVERY			
			UnOp		BATCH				PROCESS				PRODUCT		TOTAL PROTEIN	
				OFFSET (HRS)	UnOp START	UnOp END	OFFSET (HRS)		UnOp START	UnOp END	OFFSET (HRS)	SWR	OAR	SWR	OAR
1	1	INOCULUM PREP	1		3	1	6		1						
2	2	FLASK GROWTH	1		3	1	6		1						
3	53	SEED FERMENTATION	1		3	1	6		1						
4	3	PRODUCTION FERMENTATION	1		3	1	6		1			100%	100%	100%	100%
5	51	HEAT EXCHANGE	1		3	1	6		1			100%	100%	100%	100%
6	28	CONT. CENTRIFUGATION/WHOLE CELL HARVEST	1		3	1	6		1			95%	95%	95%	95%
7	48	RESUSPEND CELL PASTE	1		1				1			100%	95%	100%	95%
8	51	HEAT EXCHANGE	1		3	8	10		1			100%	95%	100%	95%
9	31	CELL DISRUPTION/HIGH PRESSURE	1		3	8	10		1			80%	76%	90%	86%
10	51	HEAT EXCHANGE	1		3	8	10		1			100%	76%	100%	86%
11	48	RESUSPENSION/SURFACTANT	1		2	11	12		1			100%	76%	95%	81%
12	29	CONT. CENTRIFUGATION/PRECIPITATE HARVEST	1		2	11	12		1			95%	72%	32%	26%
13	48	RESUSPENSION/BUFFER	1		1				1			100%	72%	95%	24%
14	29	ULTRAFILTRATION/CONCENTRATION/DILUTION	1		1				1			95%	69%	95%	23%
15	48	MICROFILTRATION/TANGENTIAL FLOW	1		1				1			93%	64%	95%	22%
16	36	PRODUCT ADSORPTION MPLC	1		1				1			85%	54%	33%	7%
17	34	PRODUCT ADSORPTION MPLC	1		1				1			90%	49%	40%	3%
18	39	ULTRAFILTRATION/FLOW DIALYSIS	1		1				1			95%	46%	95%	3%
19	39	PRODUCT ADSORPTION MPLC	1		1				1			85%	39%	55%	2%
20	37	ULTRAFILTRATION/FLOW DIALYSIS	1		1				1			90%	35%	95%	1%
21	39	PRODUCT ADSORPTION MPLC	1		1				1			90%	32%	80%	1%
22	37	MICROFILTRATION/DEAD END	1		1				1			95%	30%	95%	1%
23	99	END													
			302	304	306	308	310	312	314	316	318	320	322	324	326	328	330	332

Sheet 3 of 67
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FIG. 4
UNIT OPERATIONS LIST

MAMMALIAN CELL CULTURE PROCESS

UOP SEQ. NO.	CODE	UNIT OPERATION TYPE	CYCLES PER UnOp	CYCLES PER BATCH: UnOp OFFSET (HRS)	CYCLES PER BATCH: UnOp START	CYCLES PER BATCH: UnOp END	CYCLES PER BATCH: OFFSET (HRS)	CYCLES PER PROCESS	CYCLES PER PROCESS: UnOp START	CYCLES PER PROCESS: UnOp END	CYCLES PER PROCESS: OFFSET (HRS)	RECOVERY: PRODUCT SWR	RECOVERY: PRODUCT OAR	RECOVERY: TOTAL PROTEIN SWR	RECOVERY: TOTAL PROTEIN OAR
1	4	INITIAL SEEDING	1		1			1							
2	5	CULTURE VESSEL SPLIT	1		1			1							
3	5	CULTURE VESSEL SPLIT	1		1			1							
4	5	CULTURE VESSEL SPLIT	1		1			1							
5	6	SPINNER FLASK SPLIT	1		1			1							
6	54	SPINNER FLASK SPLIT	1		1			1							
7	13	STIRRED TANK REACTOR	1		1			1							
8	61	HARVEST/FEED	7	24	1			8	8	18	168				
9	62	HARVEST POOL	1		1			8	8	18	168				
10	34	MF/TANGENTIAL FLOW	1		1			8	8	18	168				
11	36	UF/CONCENTRATION	1		1			8	8	18	168				
12	39	PAC/MPLC	1		1			8	8	18	168				
13	39	PAC/MPLC	1		1			8	8	18	168				
14	36	UF/CONCENTRATION	1		1			8	8	18	168				
15	39	PAC/MPLC	1		1			8	8	18	168				
16	37	UF/FLOW DIALYSIS	1		1			8	8	18	168				
17	39	PAC/MPLC	1		1			8	8	18	168				
18	35	MF/DEAD END	1		1			8	8	18	168				
19	99	END	1		1			8	8	18	168				

402 404 406 408 410 412 414 416 418 420 422 424

Sheet 4 of 67
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FIG. 5

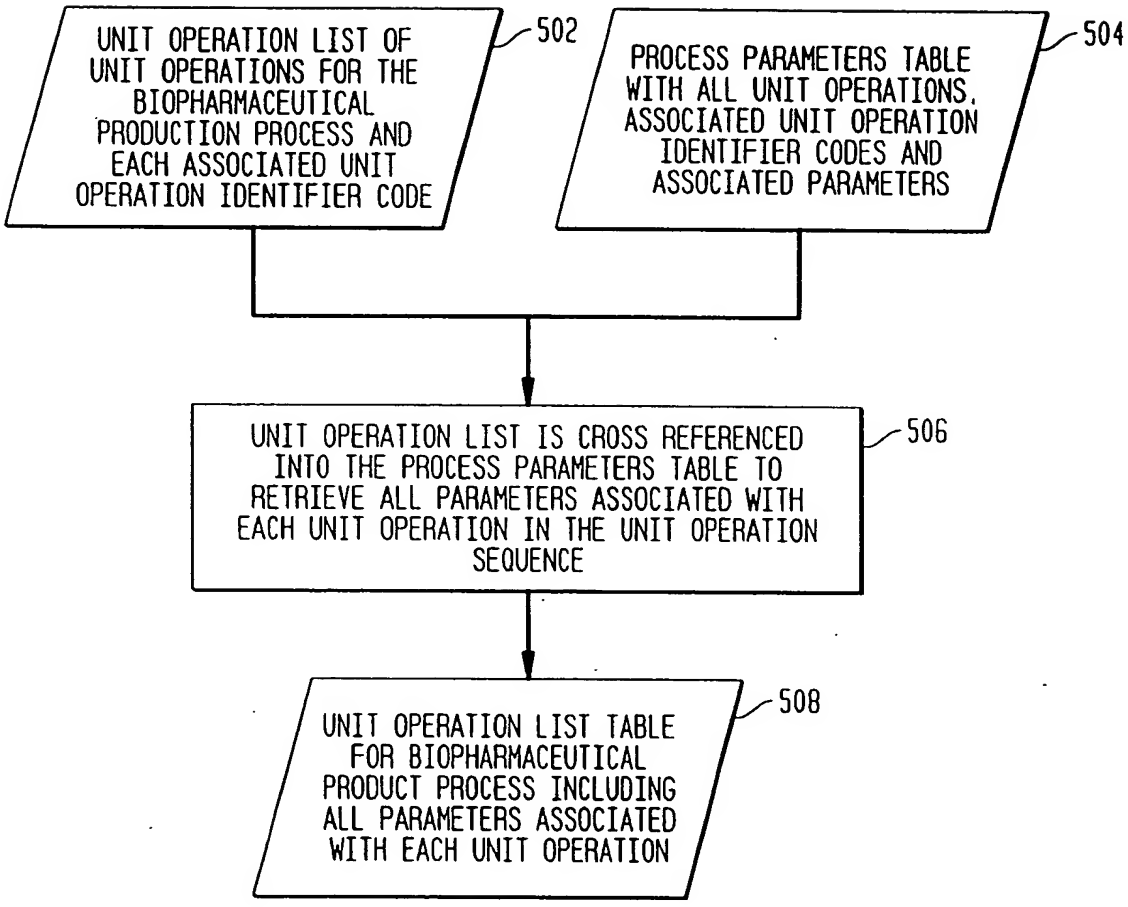

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FIG. 6A

UNIT OPERATION ID CODE	UNIT OPERATION TYPE	PARAMETERS
1	INOCULUM PREP	# OF FLASKS, VOLUME OF FLASKS, TEMPERATURE, AGITATION, DURATION, FINAL OD
2	FLASK GROWTH	SCALE UP RATIO, MEDIA VOLUME, TEMPERATURE, AGITATION, DURATION, FINAL OD
3	FERMENTATION SEED	SCALE UP RATIO, FERMENTOR WORKING VOLUME, ANTIFOAM, BASE ACID, GROW TEMPERATURE, AGITATION, SPARGE RATE, BACK PRESSURE, TOTAL DURATION
4	FERMENTATION PRODUCTION	SCALE UP RATIO, GERMENTOR WORKING VOLUME, ANTIFOAM A, ANTIFOAM B, BASE, ACID, GROW TEMPERATURE, AGITATION, SPARGE RATE, BACK PRESSURE, TOTAL DURATION, FINAL OK, DRY CELL MASS, PRODUCT CONCENTRATION, CIP, SIP
5	HEAT EXCHANGE	PROCESS INITIAL & FINAL TEMP; UTILITY INITIAL & FINAL TEMP; PROCESS SPECIFIC HEAT; DESIGN TYPE, STEP RECOVERY OF PRODUCT, STEP RECOVERY OF T.P., TEMPERATURE REGULATION, CIP, SIP
6	BATCH CENTRIFUGATION	SYSTEM VOID VOLUME, RCF, TIME, VOLUME REDUCTION, WASH VOLUME, CLEAN, RINSE
7	RESOLUBLIZATION RESUSPENSION	REAGENT/PRODUCT RATIO, TITRATION SOLUTION, RESOLUBLIZATION, AGITATION, SOLUTION NAME, STEP RECOVERY OF THE PRODUCT, STEP RECOVERY OF T.P., TEMPERATURE REGULATION, CIP, SIP
8	CELL DISRUPTION HIGH PRESS. HOMOGENIZATION	PRODUCT TERMPERATURE, UNILITY TEMPERATURE, VOID VOLUME, NUMBER OF PASSES, PRESSURE, FLOW RATE, TEMPERATURE INCREASE, WASH, RINSE, STEP RECOVERY OF PRODUCT, STEP RECOVERY OF T.P., TERMPERATURE REGULATION, CIP
9	DILUTE WITH SURFACTANT	REAGENT PRODUCT RATIO, TITRATION SOLUTION, DILUTION TIME, AGITATION, SOLUTION NAME, STEP RECOVERY OF PRODUCT, STEP RECOVERY OF T.P., TEMPERATURE REGULATION, CIP, SIP
10	BATCH CENTRIFUGATION PRECIPITATE HARVEST	SYSTEM VOID VOLUME, RCF, TIME, VOLUME REDUCTION, WASH VOLUME, CLEAN, RINSE, STEP RECOVERY OF PRODUCT, STEP RECOVERY OF T.P., TEMPERATURE REGULATION, CIP, SIP
11	RESUSPEND WITH CHAOTROPE	REAGENT/PRODUCT RATIO, TITRATION SOLUTION, RESOLUBLIZATION, AGITATION, SOLUTION NAME, STEP RECOVERY OF PRODUCT, STEP RECOVERY TO TP, TEMPERATURE REGULATION, CIP, SIP
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FIG. 6B

504

SOLUTION TYPE	TASKS	TASK DURATION
S-101	SETUP, PREINCUBATION, INCUBATION, CLEAN UP	3, 3, 23, .3, HRS
S-101	SETUP, PREINCUBATION, INCUBATION, CLEAN UP	1, 1, 23, .3, HRS
S-101, 102, 103, 104, 105	SETUP, PREINCUBATION, FERMENTATION, HARVEST, CIP, SIP, CLEAN UP	1, 1, 21, .5, 1, 1, 3 HRS
S-101, 102 103, 104, 105	SETUP, PREINCUBATION, FERMENTATION, CIP, SIP, CLEAN UP	.
	SETUP, TRANSFER, CIP, SIP, CLEAN UP	.
S-106	SETUP, CENTRIFUGATION, WASH, CIP, SIP, CLEANUP	.
S-107	SETUP, DILUTION, AGITATE, CIP, SIP, CLEAN UP	.
S-107	SETUP, LYSIS, CIP, SIP, CLEAN UP	.
S-108	SETUP, DILUTION, AGITATE, CIP, SIP, CLEAN UP	.
S-108	SETUP, CENTRIFUGATION, WASH, CIP, SIP, CLEAN UP	.
S-109	SETUP, FLUSH, PRIME, CONCENTRATION, DILUTION, WASH, FLUSH, STORE, CIP, SIP, CLEANUP	.
.	.	.

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FIG. 7

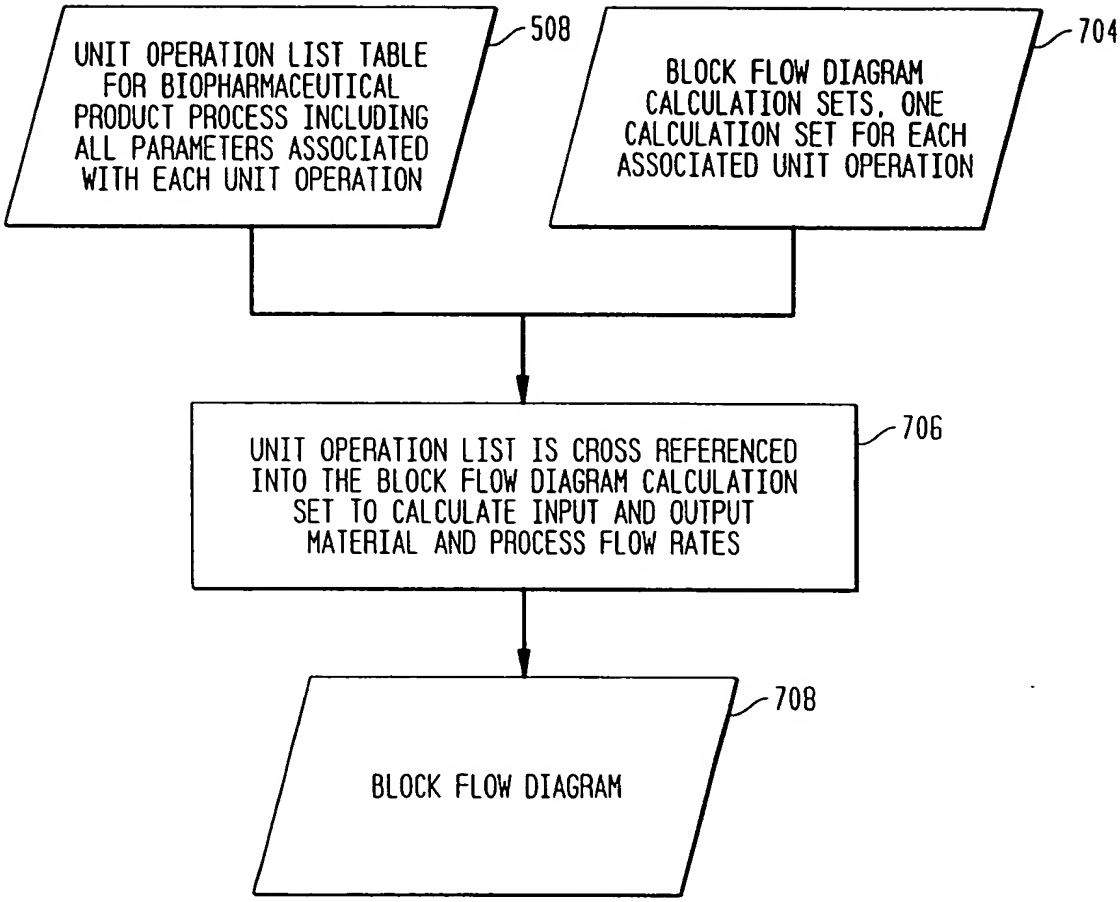

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FIG. 8

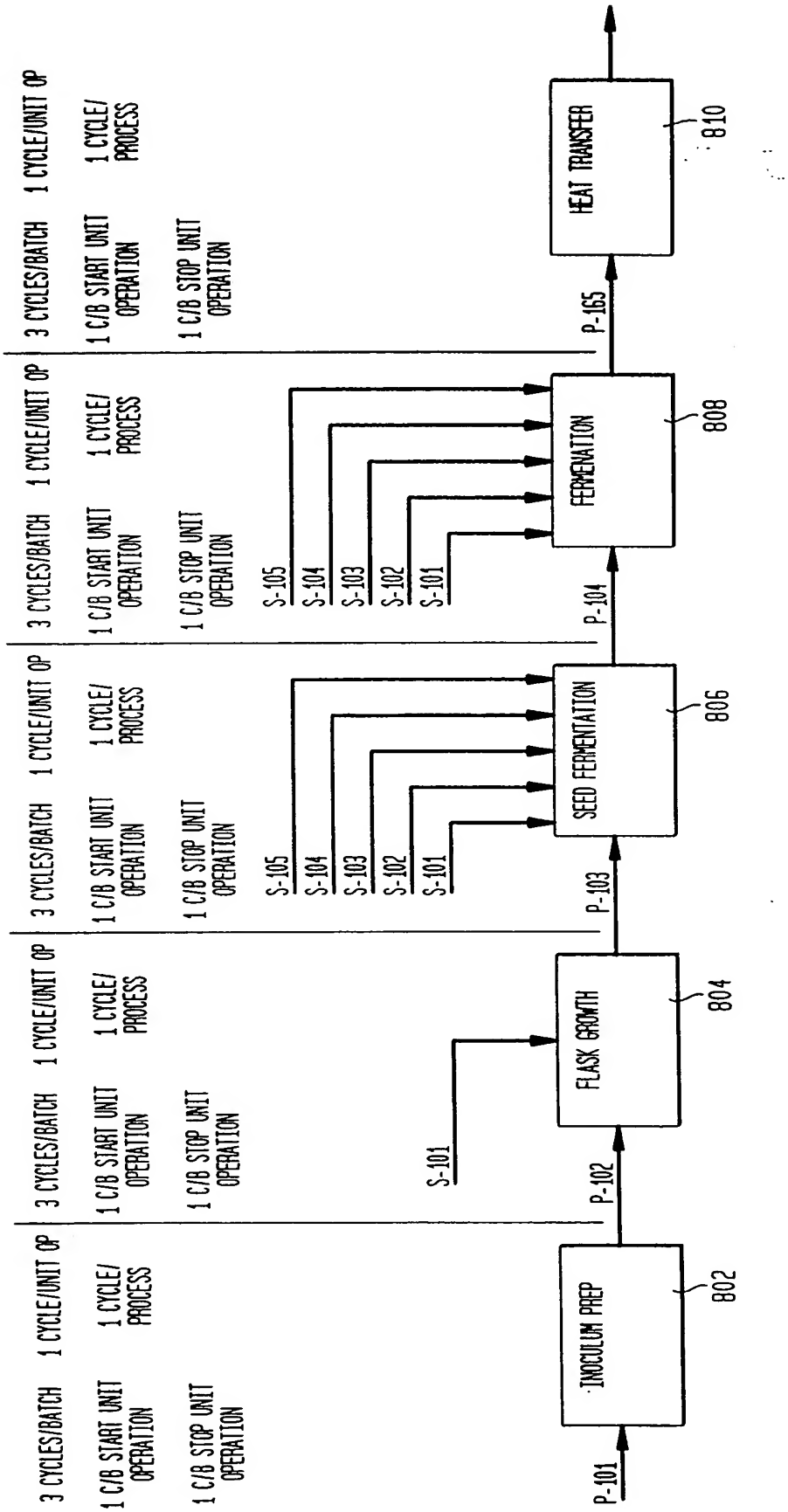

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FIG. 9

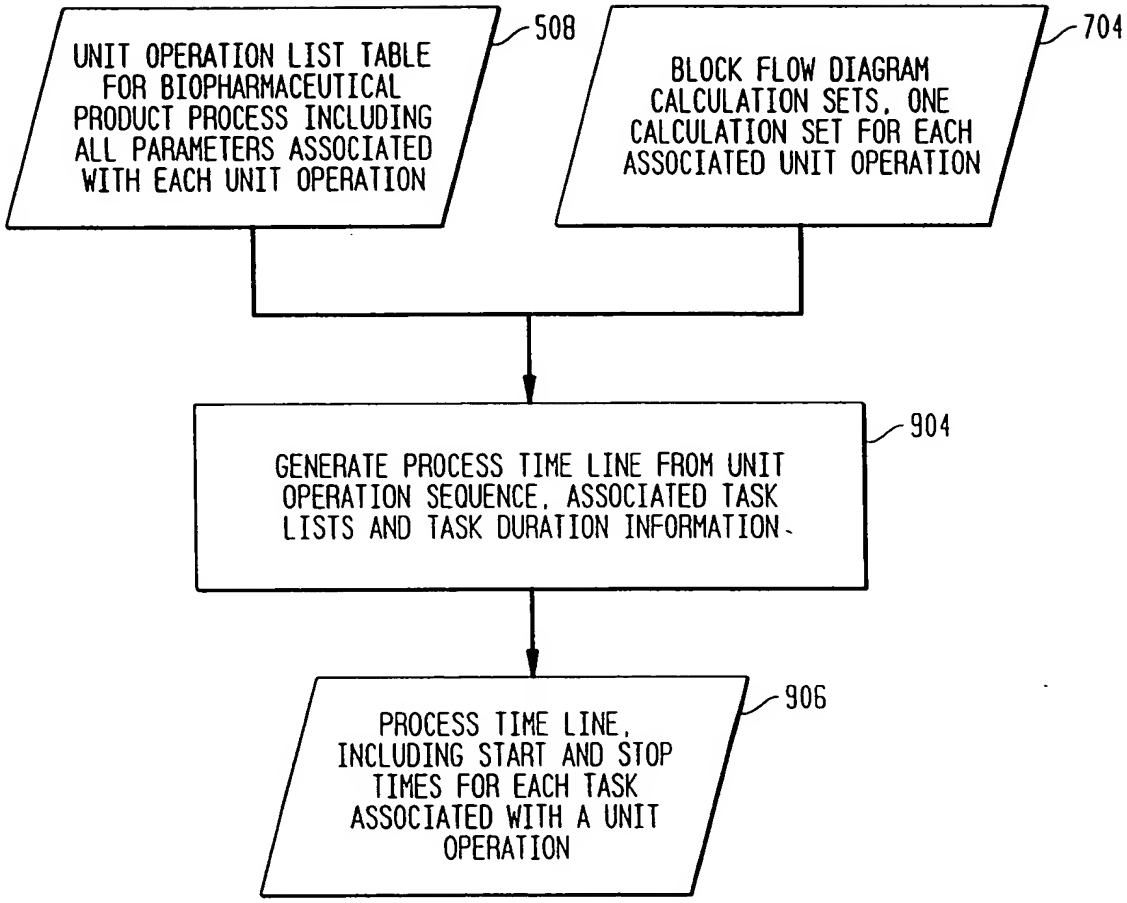

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FIG. 10

SAMPLE APPLICATION OF PROCESS DESIGN CYCLES IN PROCESS SCHEDULING

MICROBIAL FERMENTATION PROCESS (SEE UNIT OPERATION LIST)

			FIRST PROCESS CYCLE		SECOND PROCESS CYCLE	
		DURATION	WEEK	DAY	WEEK	DAY
NOTE: NONE OF THE UNIT OPERATIONS IN THIS PROCESS HAVE MORE THAT 1 CYCLE PER UNIT OPERATION (SEE UNIT OPERATION 8 IN THE MAMMALIAN CELL CULTURE PROCESS FOR AN EXAMPLE OF MULTIPLE CYCLES PER UNIT OPERATION)						
UNIT OPERATIONS 1-6 UNDERGO THREE REPETATIVE CYCLES PER BATCH AS A SET BEFORE CONTINUING WITH UNIT OP 7 THIS TRANSLATES TO THREE RUNS ON A FERMENTOR WITH EACH HARVEST (UNIT OP 5 & 6) BEING STORED FOR POOLING AT UNIT OP 7 ASSOCIATED WITH EACH FERMENTOR RUN (UNIT OP 4) ARE THE PREVIOUS STEPS FOR INNOCULATION PREP (UNIT OPS 1-3)						
1/3 FERMENTATION CYCLES PER BATCH						
1	INOCULUM PREP	24 HRS	1 FRI - SAT		2 FRI - SAT	
2	FLASK GROWTH	24 HRS	2 SAT - SUN		3 SAT - SUN	
3	SEED FERMENTAION	24 HRS	2 SUN - MON		3 SUN - MON	
4	PRODUCTION FERMENTATION	24 HRS	2 MON - TUE		3 MON - TUE	
5	HEAT EXCHANGE	1 HR	2 TUE		3 TUE	
6	CENTRIFUGATION	1 HR	2 TUE		3 TUE	
2/3 FERMENTATION CYCLES PER BATCH						
1	INOCULUM PREP	24 HRS	2 SUN - MON		3 SUN - MON	
2	FLASK GROWTH	24 HRS	2 MON - TUE		3 MON - TUE	
3	SEED FERMENTAION	24 HRS	2 TUE - WED		3 TUE - WED	
4	PRODUCTION FERMENTATION	24 HRS	2 WED - THU		3 WED - THU	
5	HEAT EXCHANGE	1 HR	2 THU		3 THU	
6	CENTRIFUGATION	1 HR	2 THU		3 THU	
3/3 FERMENTATION CYCLES PER BATCH						
1	INOCULUM PREP	24 HRS	2 TUE - WED		3 TUE - WED	
2	FLASK GROWTH	24 HRS	2 WED - THU		3 WED - THU	
3	SEED FERMENTAION	24 HRS	2 THU - FRI		3 THU - FRI	
4	PRODUCTION FERMENTATION	24 HRS	2 FRI - SAT		3 FRI - SAT	
5	HEAT EXCHANGE	1 HR	2 SAT		3 SAT	
6	CENTRIFUGATION	1 HR	2 SAT		3 SAT	
UNIT OPERATION 7 POOLS THE HARVESTS FROM THE THREE FERMENTATION CYCLES ABOVE						
7	POOL HARVESTS	3 HR	3 MON		4 MON	
UNIT OPERATIONS 8-9 UNDERGO THREE REPETATIVE CYCLES PER BATCH AS SET BEFORE CONTINUING WITH UNIT OPERATION 11 THIS TRANSLATES TO THREE CONSECUTIVE PASSES THROUGH CELL DISRUPTOR (UNIT OP 9) WITH ITS ASSOCIATED HEAT EXCHANGERS (UNIT OP 8 & 10) AT THE INLET AND THE OUTLET OF THE CELL DISRUPTOR						
1/3 DISRUPTION CYCLES PER BATCH						
8	HEAT EXCHANGE					
9	CELL DISRUPTION					
10	HEAT EXCHANGE	0.5 HR	3 MON		4 MON	
2/3 DISRUPTION CYCLES PER BATCH						
8	HEAT EXCHANGE					
9	CELL DISRUPTION					
10	HEAT EXCHANGE	0.5 HR	3 MON		4 MON	
3/3 DISRUPTION CYCLES PER BATCH						
8	HEAT EXCHANGE					
9	CELL DISRUPTION					
10	HEAT EXCHANGE	0.5 HR	3 MON		4 MON	

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FIG. 11

SAMPLE APPLICATION OF PROCESS DESIGN CYCLES IN PROCESS SCHEDULING

MICROBIAL FERMENTATION PROCESS (SEE UNIT OPERATION LIST)

			FIRST PROCESS CYCLE	SECOND PROCESS CYCLE
		DURATION	WEEK DAY	WEEK DAY
UNIT OPS 11-12 UNDERGO TWO REPETATIVE CYCLES PER BATCH AS A SET BEFORE CONTINUING WITH UNIT OP 13 THIS TRANSLATES TO TWO CYCLES OF RESUSPENDING THE CELL TYSATE FROM THE CELL DISRUPTOR IN A MILD SURFACTANT AND RECONCENTRATING THE INSOLUBLE PRODUCT TO A PASTE BY CENTRIFUGATION				
1/2 PRODUCT WASHING CYCLES PER BATCH				
11	RESUSPENSION	0.5 HR	3 MON	4 MON
12	CENTRIFUGATION	1 HR	3 MON	4 MON
2/3 PRODUCT WASHING CYCLES PER BATCH				
11	RESUSPENSION	0.5 HR	3 MON	4 MON
12	CENTRIFUGATION	1 HR	3 MON	4 MON
UNIT OPS 13-22 UNDERGO ONLY ONE CYCLE PER UNIT OPERATION EACH TO THE END OF THE PROCESS				
13	RESUSPENSION	0.5 HR	3 MON	4 MON
14	BUFFER EXCHANGE	2 HR	3 MON	4 MON
15	FILTRATION	2 HR	3 MON	4 MON
16	LIQUID CHROMATOGRAPHY	16 HRS	3 MON - TUE	4 MON - TUE
17	LIQUID CHROMATOGRAPHY	4 HRS	3 TUE	4 TUE
18	BUFFER EXCHANGE	2 HRS	3 TUE	4 TUE
19	LIQUID CHROMATOGRAPHY	2 HRS	3 WED	4 WED
20	BUFFER EXCHANGE	2 HRS	3 WED	4 WED
21	LIQUID CHROMATOGRAPHY	2 HRS	3 WED	4 WED
22	FILTRATION	2 HRS	3 WED	4 WED

FIG. 12A-1

	OPERATION	PROCESS TIME LINE												CALCULATIONS
		DURATION (HRS.)			REL. TIME SCALE (HRS)			ABS. DAYS		START		FINISH		
		CALC.	A/D	ADJ.	PREP	EXEC.	COMPL.	START	END	DATE	TIME	DATE	TIME	
						15.5				06/03/96	08:00 AM			
1	1 A INOCULUM PREP													
2														
3	SET UP	3.0	0.0	3.0 HRS	12.5			0.40	0.52	06/03/96	09:30 AM	06/03/96	12:30 PM	
4	PREINCUBATION	3.0	0.0	3.0 HRS	15.5			0.52	0.65	06/03/96	12:30 PM	06/03/96	03:30 PM	
5	INCUBATION	23.0	0.0	23.0 HRS		38.5		0.65	1.60	06/03/96	03:30 PM	06/04/96	02:30 PM	
6	CLEAN UP	0.3	0.0	0.3 HRS			38.8	1.60	1.61	06/04/96	02:30 PM	06/04/96	02:45 PM	
6	SUBTOTAL	29.0		29.0 HRS		38.5								
7														
8	2 A FLASK GROWTH													
9														
10	SET UP	1.0	0.0	1.0 HRS	37.5			1.52	1.56	06/04/96	12:30 PM	06/04/96	01:30 PM	
11	PREINCUBATION	1.0	0.0	1.0 HRS	38.5			1.56	1.60	06/04/96	01:30 PM	06/04/96	02:30 PM	
12	INCUBATION	23.0	0.0	23.0 HRS		61.5		1.60	2.56	06/04/96	02:30 PM	06/05/96	01:30 PM	
13	CLEAN UP	0.3	0.0	0.3 HRS			61.8	2.56	2.57	06/05/96	01:30 PM	06/05/96	01:45 PM	
13	SUBTOTAL	25.0		25.0 HRS		61.5								
14														
15	3 A SEED FERMENTATION													
16														
17	SET UP	1.0	0.0	1.0 HRS	60.5			2.48	2.52	06/05/96	11:30 AM	06/05/96	12:30 PM	
18	PREINCUBATION	1.0	0.0	1.0 HRS	61.5			2.52	2.56	06/05/96	12:30 PM	06/05/96	01:30 PM	
19	FERMENTATION	21.0	0.0	21.0 HRS		82.5		2.56	3.44	06/05/96	01:30 PM	06/06/96	10:30 AM	
20	HARVEST	0.5	0.0	0.5 HRS		83.0		3.44	3.46	06/06/96	10:30 AM	06/06/96	11:00 AM	50.0 L 1.7 LPM = 0.50 HRS
21	CIP	1.0	0.0	1.0 HRS			83.5	3.44	3.48	06/06/96	10:30 AM	06/06/96	11:30 AM	
22	SIP	1.0	0.0	1.0 HRS			84.5	3.48	3.52	06/06/96	11:30 AM	06/06/96	12:30 PM	
23	CLEAN UP	3.0	0.0	3.0 HRS			87.5	3.52	3.65	06/06/96	12:30 PM	06/06/96	03:30 PM	
24	SUBTOTAL	28.5		28.5 HRS		83.0								
25														

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FIG. 12A-2

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
26	4 A PRODUCTION FERMENTATION													
27														
28	SET UP	1.0	0.0	1.0 HRS	82.5			3.38	3.42	06/06/96	09:00 AM	06/06/96	10:00 AM	
29	PREINCUBATION	1.0	0.0	1.0 HRS	83.0			3.42	3.46	06/06/96	10:00 AM	06/06/96	11:00 AM	
30	FERMENTATION	21.0	0.0	21.0 HRS		104.0		3.46	4.33	06/06/96	11:00 AM	06/07/96	08:00 AM	
31	CIP	1.0	0.0	1.0 HRS			105.0	4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	
32	SIP	1.0	0.0	1.0 HRS			106.0	4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	
33	CLEAN UP	2.0	0.0	2.0 HRS			108.0	4.42	4.50	06/07/96	10:00 AM	06/07/96	12:00 PM	
34	SUBTOTAL	27.0		27.0 HRS		104.0								
35														
36	5 A HEAT EXCHANGE													
37														
38	SET UP	0.50	0.0	0.5 HRS	104.5			4.33	4.35	06/07/96	08:00 AM	06/07/96	08:30 AM	
39	TRANSFER	1.00	0.0	1.0 HRS		105.0		4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	562.1 L@ 9.4 LPM = 1.00 HRS
40	CIP	1.0	0.0	1.0 HRS			106.0	4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	
41	SIP	1.0	0.0	1.0 HRS			107.0	4.42	4.46	06/07/96	10:00 AM	06/07/96	11:00 AM	
42	CLEAN UP	2.0	0.0	2.0 HRS			109.0	4.46	4.54	06/07/96	11:00 AM	06/07/96	01:00 PM	
43	SUBTOTAL	5.0		5.0 HRS		105.0								
44														
45	6 A CONT. CENT./SOLIDS													
46														
47	SET UP	1.00	0.0	1.0 HRS	105.0			4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	
48	CENTRIFUGATION	1.00	0.0	1.0 HRS		106.0		4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	562.1 L@ 9.4 LPM = 1.00 HRS
49	WASH	0.10	0.0	0.1 HRS		106.1		4.42	4.42	06/07/96	10:00 AM	06/07/96	10:06 AM	1.0 L@ 0.2 LPM = 0.10 HRS
50	CIP	0.25	0.0	0.3 HRS			106.4	4.42	4.43	06/07/96	10:06 AM	06/07/96	10:21 AM	20.0 L@ 1.3 LPM = 0.25 HRS
51	SIP	1.00	0.0	1.0 HRS			107.4	4.43	4.47	06/07/96	10:21 AM	06/07/96	11:21 AM	
52	CLEAN UP	0.50	0.0	0.5 HRS			107.9	4.47	4.49	06/07/96	11:21 AM	06/07/96	11:51 AM	
53	SUBTOTAL	3.85		3.85 HRS		106.1								
54														
55	1 B INOCULUM PREP													
56														
57	SET UP	1.0	0.0	1.0 HRS	14.5			0.56	0.60	06/03/96	01:30 PM	06/03/96	02:30 PM	
58	PREINCUBATION	1.0	0.0	1.0 HRS	15.5			0.60	0.65	06/03/96	02:30 PM	06/03/96	03:30 PM	

FIG. 12B-1

	OPERATION	PROCESS TIME LINE						ABS. DAYS		START		FINISH		CALCULATIONS
		DURATION (HRS.)			REL. TIME SCALE (HRS)									
		CALC.	A/D	ADJ.	PREP	EXEC.	COMPL.	START	END	DATE	TIME	DATE	TIME	
						15.5				06/03/96	08:00 AM			
59	INCUBATION	23.0	0.0	23.0 HRS		38.5		0.65	1.60	06/03/96	03:30 PM	06/04/96	02:30 PM	
60	CLEAN UP	0.3	0.0	0.3 HRS			38.8	1.60	1.61	06/04/96	02:30 PM	06/04/96	02:45 PM	
60	SUBTOTAL	25.0		25.0 HRS		38.5								
61														
62	2 B FLASK GROWTH													
63														
64	SET UP	1.0	0.0	1.0 HRS	37.5			1.52	1.56	06/04/96	12:30 PM	06/04/96	01:30 PM	
65	PREINCUBATION	1.0	0.0	1.0 HRS	38.5			1.56	1.60	06/04/96	01:30 PM	06/04/96	02:30 PM	
66	INCUBATION	23.0	0.0	23.0 HRS		61.5		1.60	2.56	06/04/96	02:30 PM	06/05/96	01:30 PM	
67	CLEAN UP	0.3	0.0	0.3 HRS			61.8	2.56	2.57	06/05/96	01:30 PM	06/05/96	01:45 PM	
67	SUBTOTAL	25.0		25.0 HRS		61.5								
68														
69	3 B SEED FERMENTATION													
70														
71	SET UP	1.0	0.0	1.0 HRS	60.5			2.48	2.52	06/05/96	11:30 AM	06/05/96	12:30 PM	
72	PREINCUBATION	1.0	0.0	1.0 HRS	61.5			2.52	2.56	06/05/96	12:30 PM	06/05/96	01:30 PM	
73	FERMENTATION	21.0	0.0	21.0 HRS		82.5		2.56	3.44	06/05/96	01:30 PM	06/06/96	10:30 AM	
74	HARVEST	0.5	0.0	0.5 HRS		83.0		3.44	3.46	06/06/96	10:30 AM	06/06/96	11:00 AM	50.0 L 1.7 LPM = 0.50 HRS
75	CIP	1.0	0.0	1.0 HRS			83.5	3.44	3.48	06/06/96	10:30 AM	06/06/96	11:30 AM	
76	SIP	1.0	0.0	1.0 HRS			84.5	3.48	3.52	06/06/96	11:30 AM	06/06/96	12:30 PM	
77	CLEAN UP	3.0	0.0	3.0 HRS			87.5	3.52	3.65	06/06/96	12:30 PM	06/06/96	03:30 PM	
78	SUBTOTAL	28.5		28.5 HRS		83.0								
79														
80	4 B PRODUCTION FERMENTATION													
81														
82	SET UP	1.0	0.0	1.0 HRS	82.0			3.38	3.42	06/06/96	09:00 AM	06/06/96	10:00 AM	
83	PREINCUBATION	1.0	0.0	1.0 HRS	83.0			3.42	3.46	06/06/96	10:00 AM	06/06/96	11:00 AM	
84	FERMENTATION	21.0	0.0	21.0 HRS		104.0		3.46	4.33	06/06/96	11:00 AM	06/07/96	08:00 AM	

Sheet 15 of 67
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FIG. 12B-2

85	CIP	1.0	0.0	1.0 HRS			105.0	4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM					
86	SIP	1.0	0.0	1.0 HRS			106.0	4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM					
87	CLEAN UP	2.0	0.0	2.0 HRS			108.0	4.42	4.50	06/07/96	10:00 AM	06/07/96	12:00 PM					
88	SUBTOTAL	27.0		27.0 HRS		104.0												
89																		
90	5 B HEAT EXCHANGE																	
91																		
92	SET UP	0.50	0.0	0.5 HRS	104.5			4.33	4.35	06/07/96	08:00 AM	06/07/96	08:30 AM					
93	TRANSFER	1.00	0.0	1.0 HRS		105.0		4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	562.1 L@	9.4 LPM	=	1.00 HRS	
94	CIP	1.0	0.0	1.0 HRS			106.0	4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM					
95	SIP	1.0	0.0	1.0 HRS			107.0	4.42	4.46	06/07/96	10:00 AM	06/07/96	11:00 AM					
96	CLEAN UP	2.0	0.0	2.0 HRS			109.0	4.46	4.54	06/07/96	11:00 AM	06/07/96	01:00 PM					
97	SUBTOTAL	5.0		5.0 HRS		105.0												
98																		
99	6 B CONT. CENT./SOLIDS																	
100																		
101	SET UP	1.00	0.0	1.0 HRS	105.0			4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM					
102	CENTRIFUGATION	1.00	0.0	1.0 HRS		106.0		4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	562.1 L@	9.4 LPM	=	1.00 HRS	
103	WASH	0.10	0.0	0.1 HRS		106.1		4.42	4.42	06/07/96	10:00 AM	06/07/96	10:06 AM	1.0 L@	0.2 LPM	=	0.10 HRS	
104	CIP	0.25	0.0	0.3 HRS			106.4	4.42	4.43	06/07/96	10:06 AM	06/07/96	10:21 AM	20.0 L@	1.3 LPM	=	0.25 HRS	
105	SIP	1.00	0.0	1.0 HRS			107.4	4.43	4.47	06/07/96	10:21 AM	06/07/96	11:21 AM					
106	CLEAN UP	0.50	0.0	0.5 HRS			107.9	4.47	4.49	06/07/96	11:21 AM	06/07/96	11:51 AM					
107	SUBTOTAL	3.85		3.85 HRS		106.1												
108																		
109	1 C INOCULUM PREP																	
110																		
111	SET UP	1.0	0.0	1.0 HRS	14.5			0.56	0.50	06/03/96	01:30 PM	06/03/96	02:30 PM					
112	PREINCUBATION	1.0	0.0	1.0 HRS	15.5			0.60	0.65	06/03/96	02:30 PM	06/03/96	03:30 PM					
113	INCUBATION	23.0	0.0	23.0 HRS		38.5		0.65	1.60	06/03/96	03:30 PM	06/04/96	02:30 PM					
114	CLEAN UP	0.3	0.0	0.3 HRS			38.8	1.60	1.61	06/04/96	02:30 PM	06/04/96	02:45 PM					
114	SUBTOTAL	25.0		25.0 HRS		38.5												
115																		

FIG. 12C-1

	OPERATION	PROCESS TIME LINE												CALCULATIONS
		DURATION (HRS.)			REL. TIME SCALE (HRS)			ABS. DAYS		START		FINISH		
		CALC.	A/D	ADJ.	PREP	EXEC.	COMPL.	START	END	DATE	TIME	DATE	TIME	
						15.5				06/03/96	08:00 AM			
116	2 C FLASK GROWTH													
117														
118	SET UP	1.0	0.0	1.0 HRS	37.5			1.52	1.56	06/04/96	12:30 PM	06/04/96	01:30 PM	
119	PREINCUBATION	1.0	0.0	1.0 HRS	38.5			1.56	1.60	06/04/96	01:30 PM	06/04/96	02:30 PM	
120	INCUBATION	23.0	0.0	23.0 HRS		61.5		1.60	2.56	06/04/96	02:30 PM	06/05/96	01:30 PM	
121	CLEAN UP	0.3	0.0	0.3 HRS			61.8	2.56	2.57	06/05/96	01:30 PM	06/05/96	01:45 PM	
121	SUBTOTAL	25.0		25.0 HRS		61.5								
122														
123	3 C SEED FERMENTATION													
124														
125	SET UP	1.0	0.0	1.0 HRS	60.5			2.48	2.52	06/05/96	11:30 AM	06/05/96	12:30 PM	
126	PREINCUBATION	1.0	0.0	1.0 HRS	61.5			2.52	2.56	06/05/96	12:30 PM	06/05/96	01:30 PM	
127	FERMENTATION	21.0	0.0	21.0 HRS		82.5		2.56	3.44	06/05/96	01:30 PM	06/06/96	10:30 AM	
128	HARVEST	0.5	0.0	0.5 HRS		83.0		3.44	3.46	06/06/96	10:30 AM	06/06/96	11:00 AM	50.0 L 1.7 LPM = 0.50 HRS
129	CIP	1.0	0.0	1.0 HRS			83.5	3.44	3.48	06/06/96	10:30 AM	06/06/96	11:30 AM	
130	SIP	1.0	0.0	1.0 HRS			84.5	3.48	3.52	06/06/96	11:30 AM	06/06/96	12:30 PM	
131	CLEAN UP	3.0	0.0	3.0 HRS			87.5	3.52	3.65	06/06/96	12:30 PM	06/06/96	03:30 PM	
132	SUBTOTAL	28.5		28.5 HRS		83.0								
133														
134	4 C PRODUCTION FERMENTATION													
135														
136	SET UP	1.0	0.0	1.0 HRS	82.0			3.38	3.42	06/06/96	09:00 AM	06/06/96	10:00 AM	
137	PREINCUBATION	1.0	0.0	1.0 HRS	83.0			3.42	3.46	06/06/96	10:00 AM	06/06/96	11:00 AM	
138	FERMENTATION	21.0	0.0	21.0 HRS		104.0		3.46	4.33	06/06/96	11:00 AM	06/07/96	08:00 AM	
139	CIP	1.0	0.0	1.0 HRS			105.0	4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	
140	SIP	1.0	0.0	1.0 HRS			106.0	4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	
141	CLEAN UP	2.0	0.0	2.0 HRS			108.0	4.42	4.50	06/07/96	10:00 AM	06/07/96	12:00 PM	
142	SUBTOTAL	27.0		27.0 HRS		104.0								

Sheet 17 of 67
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FIG. 12C-2

143																	
144	5 C HEAT EXCHANGE																
145																	
146	SET UP	0.50	0.0	0.5 HRS	104.5			4.33	4.35	06/07/96	08:00 AM	06/07/96	08:30 AM				
147	TRANSFER	1.00	0.0	1.0 HRS		105.0		4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM	562.1 L@	9.4 LPM	=	1.00 HRS
148	CIP	1.0	0.0	1.0 HRS			106.0	4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM				
149	SIP	1.0	0.0	1.0 HRS			107.0	4.42	4.46	06/07/96	10:00 AM	06/07/96	11:00 AM				
150	CLEAN UP	2.0	0.0	2.0 HRS			109.0	4.46	4.54	06/07/96	11:00 AM	06/07/96	01:00 PM				
151	SUBTOTAL	5.0		5.0 HRS		105.0											
152																	
153	6 C CONT. CENT./SOLIDS																
154																	
155	SET UP	1.00	0.0	1.0 HRS	105.0			4.33	4.38	06/07/96	08:00 AM	06/07/96	09:00 AM				
156	CENTRIFUGATION	1.00	0.0	1.0 HRS		106.0		4.38	4.42	06/07/96	09:00 AM	06/07/96	10:00 AM	562.1 L@	9.4 LPM	=	1.00 HRS
157	WASH	0.10	0.0	0.1 HRS		106.1		4.42	4.42	06/07/96	10:00 AM	06/07/96	10:06 AM	1.0 L@	0.2 LPM	=	0.10 HRS
158	CIP	0.25	0.0	0.3 HRS			106.4	4.42	4.43	06/07/96	10:06 AM	06/07/96	10:21 AM	20.0 L@	1.3 LPM	=	0.25 HRS
159	SIP	1.00	0.0	1.0 HRS			107.4	4.43	4.47	06/07/96	10:21 AM	06/07/96	11:21 AM				
160	CLEAN UP	0.50	0.0	0.5 HRS			107.9	4.47	4.49	06/07/96	11:21 AM	06/07/96	11:51 AM				
161	SUBTOTAL	3.85		3.85 HRS		106.1											
162																	
163	7 A RESOLUBLIZATION																
164																	
165	SET UP	1.00	0.0	1.0 HRS	106.1			4.38	4.42	06/07/96	09:06 AM	06/07/96	10:06 AM				
166	DILUTION	0.50	0.0	0.5 HRS		106.6		4.42	4.44	06/07/96	10:06 AM	06/07/96	10:36 AM	46.7 L@	1.6 LPM	=	0.50 HRS
167	AGITATE	1.00	0.0	1.0 HRS		107.6		4.44	4.48	06/07/96	10:36 AM	06/07/96	11:36 AM				0.50 HRS
168	CIP	1.00	0.0	1.0 HRS			108.6	4.48	4.53	06/07/96	11:36 AM	06/07/96	12:36 PM				
169	SIP	1.00	0.0	1.0 HRS			109.6	4.53	4.57	06/07/96	12:36 PM	06/07/96	01:36 PM				
170	CLEAN UP	1.00	0.0	1.0 HRS			110.6	4.57	4.61	06/07/96	01:36 PM	06/07/96	02:36 PM				
171	SUBTOTAL	5.50		5.50 HRS		107.6											
172																	
173	8 A HEAT EXCHANGE																
174																	

Sheet 18 of 67
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FIG. 12D-1

	OPERATION	PROCESS TIME LINE												CALCULATIONS
		DURATION (HRS.)			REL. TIME SCALE (HRS)			ABS. DAYS		START		FINISH		
		CALC.	A/D	ADJ.	PREP	EXEC.	COMPL.	START	END	DATE	TIME	DATE	TIME	
						15.5				06/03/96	08:00 AM			
175	SET UP	0.50	0.0	0.5 HRS	107.6			4.46	4.48	06/07/96	11:06 AM	06/07/96	11:36 AM	
176	TRANSFER	0.30	0.0	0.3 HRS		107.9		4.48	4.50	06/07/96	11:36 AM	06/07/96	11:54 AM	66.5 L@ 3.7 LPM = 0.30 HRS
177	CIP	0.0	0.0	0.0 HRS			107.9	4.50	4.50	06/07/96	11:54 AM	06/07/96	11:54 AM	
178	SIP	0.0	0.0	0.0 HRS			107.9	4.50	4.50	06/07/96	11:54 AM	06/07/96	11:54 AM	
179	CLEAN UP	0.0	0.0	0.0 HRS			107.9	4.50	4.50	06/07/96	11:54 AM	06/07/96	11:54 AM	
180	SUBTOTAL	0.8		0.8 HRS		107.9								
181														
182	9 A HOMMOGENIZATION													
183														
184	SET UP	0.25	0.0	0.3 HRS	107.9			4.49	4.50	06/07/96	11:39 AM	06/07/96	11:54 AM	
185	LYSIS	0.68	0.0	0.7 HRS		108.6		4.50	4.52	06/07/96	11:54 AM	06/07/96	12:34 PM	66.5 L@ 1.6 LPM = 0.68 HRS
186	CIP	0.0	0.0	0.0 HRS			108.6	4.52	4.52	06/07/96	12:34 PM	06/07/96	12:34 PM	
187	SIP	0.0	0.0	0.0 HRS			108.6	4.52	4.52	06/07/96	12:34 PM	06/07/96	12:34 PM	
188	CLEAN UP	0.0	0.0	0.0 HRS			108.6	4.52	4.52	06/07/96	12:34 PM	06/07/96	12:34 PM	
189	SUBTOTAL	0.9		0.9 HRS		108.6								
190														
191	10 A HEAT EXCHANGE													
192														
193	SET UP	0.50	0.0	0.5 HRS	108.6			4.50	4.52	06/07/96	12:04 PM	06/07/96	12:34 PM	
194	TRANSFER	0.30	0.0	0.3 HRS		108.9		4.52	4.54	06/07/96	12:34 PM	06/07/96	12:52 PM	69.0 L@ 3.8 LPM = 0.30 HRS
195	CIP	0.0	0.0	0.0 HRS			108.9	4.54	4.54	06/07/96	12:52 PM	06/07/96	12:52 PM	
196	SIP	0.0	0.0	0.0 HRS			108.9	4.54	4.54	06/07/96	12:52 PM	06/07/96	12:52 PM	
197	CLEAN UP	0.0	0.0	0.0 HRS			108.9	4.54	4.54	06/07/96	12:52 PM	06/07/96	12:52 PM	
198	SUBTOTAL	0.8		0.8 HRS		108.9								
199														
200	8 B HEAT EXCHANGE													
201														
202	SET UP	0.00	0.0	0.0 HRS	108.9			4.54	4.54	06/07/96	12:52 PM	06/07/96	12:52 PM	

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FIG. 12D-2

203	TRANSFER	0.30	0.0	0.3 HRS		109.2		4.54	4.55	06/07/96	12:52 PM	06/07/96	01:10 PM	66.5 LB	3.7 LPM	=	0.30 HRS
204	CIP	0.0	0.0	0.0 HRS			109.2	4.55	4.55	06/07/96	01:10 PM	06/07/96	01:10 PM				
205	SIP	0.0	0.0	0.0 HRS			109.2	4.55	4.55	06/07/96	01:10 PM	06/07/96	01:10 PM				
206	CLEAN UP	0.0	0.0	0.0 HRS			109.2	4.55	4.55	06/07/96	01:10 PM	06/07/96	01:10 PM				
207	SUBTOTAL	0.3		0.3 HRS		109.2											
208																	
209	9 B HOMMOGENIZATION																
210																	
211	SET UP	0.00	0.0	0.0 HRS	109.2			4.55	4.55	06/07/96	01:10 PM	06/07/96	01:10 PM				
212	LYSIS	0.68	0.0	0.7 HRS		109.9		4.55	4.58	06/07/96	01:10 PM	06/07/96	01:51 PM	66.5 LB	1.6 LPM	=	0.68 HRS
213	CIP	0.0	0.0	0.0 HRS			109.9	4.58	4.58	06/07/96	01:51 PM	06/07/96	01:51 PM				
214	SIP	0.0	0.0	0.0 HRS			109.9	4.58	4.58	06/07/96	01:51 PM	06/07/96	01:51 PM				
215	CLEAN UP	0.0	0.0	0.0 HRS			109.9	4.58	4.58	06/07/96	01:51 PM	06/07/96	01:51 PM				
216	SUBTOTAL	0.7		0.7 HRS		109.9											
217																	
218	10 B HEAT EXCHANGE																
219																	
220	SET UP	0.50	0.0	0.5 HRS	109.9			4.56	4.58	06/07/96	01:21 PM	06/07/96	01:51 PM				
221	TRANSFER	0.30	0.0	0.3 HRS		110.2		4.58	4.59	06/07/96	01:51 PM	06/07/96	02:09 PM	69.0 LB	3.8 LPM	=	0.30 HRS
222	CIP	0.0	0.0	0.0 HRS			110.2	4.59	4.59	06/07/96	02:09 PM	06/07/96	02:09 PM				
223	SIP	0.0	0.0	0.0 HRS			110.2	4.59	4.59	06/07/96	02:09 PM	06/07/96	02:09 PM				
224	CLEAN UP	0.0	0.0	0.0 HRS			110.2	4.59	4.59	06/07/96	02:09 PM	06/07/96	02:09 PM				
225	SUBTOTAL	0.8		0.8 HRS		110.2											
226																	
227	8 C HEAT EXCHANGE																
228																	
229	SET UP	0.00	0.0	0.0 HRS	110.2			4.59	4.59	06/07/96	02:09 PM	06/07/96	02:09 PM				
230	TRANSFER	0.30	0.0	0.3 HRS		110.5		4.59	4.60	06/07/96	02:09 PM	06/07/96	02:27 PM	66.5 LB	3.7 LPM	=	0.30 HRS
231	CIP	1.0	0.0	1.0 HRS			111.5	4.60	4.64	06/07/96	02:27 PM	06/07/96	03:27 PM				
232	SIP	1.0	0.0	1.0 HRS			112.5	4.64	4.69	06/07/96	03:27 PM	06/07/96	04:27 PM				
233	CLEAN UP	1.0	0.0	1.0 HRS			113.5	4.69	4.73	06/07/96	04:27 PM	06/07/96	05:27 PM				
234	SUBTOTAL	3.3		3.3 HRS		110.5											

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FIG. 12E-1

	OPERATION	PROCESS TIME LINE						ABS. DAYS		START		FINISH		CALCULATIONS
		DURATION (HRS.)			REL. TIME SCALE (HRS)									
		CALC.	A/D	ADJ.	PREP	EXEC.	COMPL.	START	END	DATE	TIME	DATE	TIME	
						15.5				06/03/96	08:00 AM			
235														
236	9 C HOMMOGENIZATION													
237														
238	SET UP	0.00	0.0	0.0 HRS	110.5			4.60	4.60	06/07/96	02:27 PM	06/07/96	02:27 PM	
239	LYSIS	0.68	0.0	0.7 HRS		111.1		4.60	4.63	06/07/96	02:27 PM	06/07/96	03:07 PM	66.5 L@ 1.6 LPM = 0.68 HRS
240	CIP	1.0	0.0	1.0 HRS			112.1	4.63	4.67	06/07/96	03:07 PM	06/07/96	04:07 PM	
241	SIP	1.0	0.0	1.0 HRS			113.1	4.67	4.71	06/07/96	04:07 PM	06/07/96	05:07 PM	
242	CLEAN UP	1.0	0.0	1.0 HRS			114.1	4.71	4.76	06/07/96	05:07 PM	06/07/96	06:07 PM	
243	SUBTOTAL	3.7		3.7 HRS		111.1								
244														
245	10 C HEAT EXCHANGE													
246														
247	SET UP	0.00	0.0	0.0 HRS	111.1			4.63	4.63	06/07/96	03:07 PM	06/07/96	03:07 PM	
248	TRANSFER	0.30	0.0	0.3 HRS		111.4		4.63	4.64	06/07/96	03:07 PM	06/07/96	03:25 PM	69.0 L@ 3.8 LPM = 0.30 HRS
249	CIP	1.0	0.0	1.0 HRS			112.4	4.64	4.68	06/07/96	03:25 PM	06/07/96	04:25 PM	
250	SIP	1.0	0.0	1.0 HRS			113.4	4.68	4.73	06/07/96	04:25 PM	06/07/96	05:25 PM	
251	CLEAN UP	1.0	0.0	1.0 HRS			114.4	4.73	4.77	06/07/96	05:25 PM	06/07/96	06:25 PM	
252	SUBTOTAL	3.3		3.3 HRS		111.4								
253														
254	11 A RESOLUBLIZATION													
255														
256	SET UP	1.0	0.0	1.0 HRS	108.9			4.49	4.54	06/07/96	11:52 AM	06/07/96	12:52 PM	
257	DILUTION	0.5	0.0	0.5 HRS		109.4		4.54	4.56	06/07/96	12:52 PM	06/07/96	01:22 PM	206.9 L@ 6.9 LPM = 0.50 HRS
258	AGITATE	0.5	0.0	0.5 HRS		109.9		4.56	4.58	06/07/96	01:22 PM	06/07/96	01:52 PM	0.50 HRS
259	CIP	0.0	0.0	0.0 HRS			109.9	4.58	4.58	06/07/96	01:52 PM	06/07/96	01:52 PM	
260	SIP	0.0	0.0	0.0 HRS			109.9	4.58	4.58	06/07/96	01:52 PM	06/07/96	01:52 PM	
261	CLEAN UP	0.0	0.0	0.0 HRS			109.9	4.58	4.58	06/07/96	01:52 PM	06/07/96	01:52 PM	
262	SUBTOTAL	2.0		2.0 HRS		109.9								

Sheet 21 of 67
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Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

FIG. 12E-2

263																	
264	12 A CONT. CENT/SOLIDS																
265																	
266	SET UP	1.0	0.0	1.0 HRS	109.9			4.54	4.58	06/07/96	12:52 PM	06/07/96	01:52 PM				
267	CENTRIFUGATION	0.5	0.0	0.5 HRS		110.4		4.58	4.60	06/07/96	01:52 PM	06/07/96	02:22 PM	275.9 L@	9.2 LPM	=	0.50 HRS
268	WASH	0.1	0.0	0.1 HRS		110.5		4.60	4.60	06/07/96	02:22 PM	06/07/96	02:28 PM	3.0 L@	0.5 LPM	=	0.10 HRS
269	CIP	0.0	0.0	0.0 HRS			110.5	4.60	4.60	06/07/96	02:28 PM	06/07/96	02:28 PM	8.0 L@	0.5 LPM	=	0.25 HRS
270	SIP	0.0	0.0	0.0 HRS			110.5	4.60	4.60	06/07/96	02:28 PM	06/07/96	02:28 PM				
271	CLEAN UP	0.0	0.0	0.0 HRS			110.5	4.60	4.60	06/07/96	02:28 PM	06/07/96	02:28 PM				
272	SUBTOTAL	1.6		1.6 HRS		110.5											
273																	
274	11 B RESOLUBLIZATION																
275																	
276	SET UP	0.0	0.0	0.0 HRS	110.5			4.60	4.60	06/07/96	02:28 PM	06/07/96	02:28 PM				
277	DILUTION	0.5	0.0	0.5 HRS		111.0		4.60	4.62	06/07/96	02:28 PM	06/07/96	02:58 PM	206.9 L@	6.9 LPM	=	0.50 HRS
278	AGITATE	0.3	0.0	0.3 HRS		111.2		4.62	4.63	06/07/96	02:58 PM	06/07/96	03:13 PM				0.50 HRS
279	CIP	1.0	0.0	1.0 HRS			112.2	4.63	4.68	06/07/96	03:13 PM	06/07/96	04:13 PM				
280	SIP	1.0	0.0	1.0 HRS			113.2	4.68	4.72	06/07/96	04:13 PM	06/07/96	05:13 PM				
281	CLEAN UP	1.0	0.0	1.0 HRS			114.2	4.72	4.76	06/07/96	05:13 PM	06/07/96	06:13 PM				
282	SUBTOTAL	3.8		3.8 HRS		111.2											
283																	
284	12 B CONT. CENT/SOLIDS																
285																	
286	SET UP	1.0	0.0	1.0 HRS	111.2			4.59	4.63	06/07/96	02:13 PM	06/07/96	03:13 PM				
287	CENTRIFUGATION	0.5	0.0	0.5 HRS		111.7		4.63	4.66	06/07/96	03:13 PM	06/07/96	03:43 PM	275.9 L@	9.2 LPM	=	0.50 HRS
288	WASH	0.1	0.0	0.1 HRS		111.8		4.66	4.66	06/07/96	03:43 PM	06/07/96	03:49 PM	3.0 L@	0.5 LPM	=	0.10 HRS
289	CIP	0.3	0.0	0.3 HRS			112.1	4.66	4.67	06/07/96	03:49 PM	06/07/96	04:04 PM	8.0 L@	0.5 LPM	=	0.25 HRS
290	SIP	1.0	0.0	1.0 HRS			113.1	4.67	4.71	06/07/96	04:04 PM	06/07/96	05:04 PM				
291	CLEAN UP	0.5	0.0	0.5 HRS			113.6	4.71	4.73	06/07/96	05:04 PM	06/07/96	05:34 PM				
292	SUBTOTAL	3.4		3.4 HRS		111.8											
293																	
294	13 A RESOLUBLIZATION																

Sheet 22 of 67

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FIG. 12F-1

	OPERATION	PROCESS TIME LINE												CALCULATIONS
		DURATION (HRS.)			REL. TIME SCALE (HRS)			ABS. DAYS		START		FINISH		
		CALC.	A/D	ADJ.	PREP	EXEC.	COMPL.	START	END	DATE	TIME	DATE	TIME	
						15.5				06/03/96	08:00 AM			
295														
296	SET UP	1.0	0.0	1.0 HRS	110.5			4.56	4.60	06/07/96	01:28 PM	06/07/96	02:28 PM	
297	DILUTION	0.5	0.0	0.5 HRS		111.0		4.60	4.62	06/07/96	02:28 PM	06/07/96	02:58 PM	60.7 L@ 2.0 LPM = 0.50 HRS
298	AGITATE	18.0	0.0	18.0 HRS		129.0		4.62	5.37	06/07/96	02:58 PM	06/08/96	08:58 AM	23.50 HRS
299	CIP	1.0	0.0	1.0 HRS			130.0	5.37	5.42	06/08/96	08:58 AM	06/08/96	09:58 AM	
300	SIP	1.0	0.0	1.0 HRS			131.0	5.42	5.46	06/08/96	09:58 AM	06/08/96	10:58 AM	
301	CLEAN UP	1.0	0.0	1.0 HRS			132.0	5.46	5.50	06/08/96	10:58 AM	06/08/96	11:58 AM	
302	SUBTOTAL	22.5		22.5 HRS		129.0								
303														
304	14 A CONCENTRATION													26.99 SF
305														
306	SET UP	1.0	0.0	1.0 HRS	127.6			5.28	5.32	06/08/96	06:38 AM	06/08/96	07:38 AM	
307	FLUSH	0.7	0.0	0.7 HRS	128.3			5.32	5.35	06/08/96	07:38 AM	06/08/96	08:18 AM	54.0 L@ 3.0 L/SF/Hr or 1.35 LPM
308	PRIME	0.7	0.0	0.7 HRS	129.0			5.35	5.37	06/08/96	08:18 AM	06/08/96	08:58 AM	54.0 L@ 3.0 L/SF/Hr or 1.35 LPM
309	CONCENTRATION	1.0	0.0	1.0 HRS		130.0		5.37	5.42	06/08/96	08:58 AM	06/08/96	09:58 AM	81.0 L@ 3.0 L/SF/Hr or 1.35 LPM
310	DILUTION	0.4	0.0	0.4 HRS		130.4		5.42	5.43	06/08/96	09:58 AM	06/08/96	10:25 AM	13.5 L@ 0.5 LPM
311	WASH	0.9	0.0	0.9 HRS		131.3		5.43	5.47	06/08/96	10:25 AM	06/08/96	11:19 AM	72.9 L@ 3.0 L/SF/Hr or 1.35 LPM
312	FLUSH	0.3	0.0	0.3 HRS			131.7	5.47	5.49	06/08/96	11:19 AM	06/08/96	11:39 AM	27.0 L@ 3.0 L/SF/Hr or 1.35 LPM
313	STORE	0.7	0.0	0.7 HRS			132.3	5.49	5.51	06/08/96	11:39 AM	06/08/96	12:19 PM	54.0 L@ 3.0 L/SF/Hr or 1.35 LPM
314	CIP	1.0	0.0	1.0 HRS			133.3	5.51	5.56	06/08/96	12:19 PM	06/08/96	01:19 PM	
315	SIP	1.0	0.0	1.0 HRS			134.3	5.56	5.60	06/08/96	01:19 PM	06/08/96	02:19 PM	
316	CLEAN UP	1.0	0.0	1.0 HRS			135.3	5.60	5.64	06/08/96	02:19 PM	06/08/96	03:19 PM	
317	SUBTOTAL	8.7		8.7 HRS		131.3								MAX FR 1.35 LPM
318														
319	15 A MICROFILTRATION													12.60 SF
320														
321	SET UP	1.0	0.0	1.0 HRS	131.1			5.42	5.46	06/08/96	10:03 AM	06/08/96	11:03 AM	
322	FLUSH	0.1	0.0	0.1 HRS	131.2			5.46	5.47	06/08/96	11:03 AM	06/08/96	11:11 AM	25.2 L@ 15.0 L/SF/Hr or 3.15 LPM
323	PRIME	0.1	0.0	0.1 HRS	131.3			5.47	5.47	06/08/96	11:11 AM	06/08/96	11:19 AM	25.2 L@ 15.0 L/SF/Hr or 3.15 LPM

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FIG. 12F-2

324	FILTRATION	0.5	0.0	0.5 HRS		131.8		5.47	5.49	06/08/96	11:19 AM	06/08/96	11:49 AM	94.5 L@ 15.0 L/SF/Hr or 3.15 LPM
325	WASH	0.0	0.0	0.0 HRS		131.8		5.49	5.49	06/08/96	11:49 AM	06/08/96	11:49 AM	0.0 L@ 15.0 L/SF/Hr or 3.15 LPM
326	REGENERATE	0.0	0.0	0.0 HRS			131.9	5.49	5.49	06/08/96	11:49 AM	06/08/96	11:51 AM	6.3 L@ 15.0 L/SF/Hr or 3.15 LPM
327	STORE	0.1	0.0	0.1 HRS			131.9	5.49	5.50	06/08/96	11:51 AM	06/08/96	11:55 AM	12.6 L@ 15.0 L/SF/Hr or 3.15 LPM
328	CIP	1.0	0.0	1.0 HRS			132.9	5.50	5.54	06/08/96	11:55 AM	06/08/96	12:55 PM	
329	SIP	1.0	0.0	1.0 HRS			133.9	5.54	5.58	06/08/96	12:55 PM	06/08/96	01:55 PM	
330	CLEAN UP	1.0	0.0	1.0 HRS			134.9	5.58	5.62	06/08/96	01:55 PM	06/08/96	02:55 PM	
331	SUBTOTAL	4.9		4.9 HRS		131.8								
332														
333	16 A P/A MPLC													63.8 L.CV 0.4 H/D 60.32 CM DIA.
334														
335	EQUILIBRATION	1.1	0.0	1.1 HRS	131.4			5.43	5.48	06/08/96	10:17 AM	06/08/96	11:24 AM	318.9 L@ 100.0 CM/HR or 4.76 LPM
336	LOAD	0.7	0.0	0.7 HRS		132.5		5.49	5.52	06/08/96	11:49 AM	06/08/96	12:31 PM	100.5 L@ 50.0 CM/HR or 2.38 LPM
337	WASH	1.3	0.0	1.3 HRS		133.9		5.52	5.58	06/08/96	12:31 PM	06/08/96	01:52 PM	191.4 L@ 50.0 CM/HR or 2.38 LPM
338	ELUTE A	1.3	0.0	1.3 HRS		135.2		5.58	5.63	06/08/96	01:52 PM	06/08/96	03:12 PM	191.4 L@ 50.0 CM/HR or 2.38 LPM
339	ELUTE B	0.0	0.0	0.0 HRS		135.2		5.63	5.63	06/08/96	03:12 PM	06/08/96	03:12 PM	0.0 L@ 30.0 CM/HR or 1.43 LPM
340	REGENERATE	0.2	0.0	0.2 HRS			135.4	5.63	5.64	06/08/96	03:12 PM	06/08/96	03:25 PM	63.8 L@ 100.0 CM/HR or 4.76 LPM
341	STORE	0.4	0.0	0.4 HRS			135.9	5.64	5.66	06/08/96	03:25 PM	06/08/96	03:52 PM	127.6 L@ 100.0 CM/HR or 4.76 LPM
342	CIP	1.0	0.0	1.0 HRS			136.9	5.66	5.70	06/08/96	03:52 PM	06/08/96	04:52 PM	
343	SIP	1.0	0.0	1.0 HRS			137.9	5.70	5.74	06/08/96	04:52 PM	06/08/96	05:52 PM	
344	CLEAN UP	1.0	0.0	1.0 HRS			138.9	5.74	5.79	06/08/96	05:52 PM	06/08/96	06:52 PM	
345	SUBTOTAL	5.2		5.2 HRS		135.2								MAX FR 4.76 LPM
346														
347														
348	17 A P/A MPLC													12.2 L.CV 0.4 H/D 34.75 CM DIA.
349														
350	EQUILIBRATION	0.6	0.0	0.6 HRS	135.6			5.62	5.65	06/08/96	02:59 PM	06/08/96	03:38 PM	61.0 L@ 100.0 CM/HR or 1.58 LPM
351	LOAD	1.1	0.0	1.1 HRS		136.3		5.63	5.68	06/08/96	03:12 PM	06/08/96	04:17 PM	51.0 L@ 50.0 CM/HR or 0.79 LPM
352	WASH	0.8	0.0	0.8 HRS		137.1		5.68	5.71	06/08/96	04:17 PM	06/08/96	05:03 PM	36.6 L@ 50.0 CM/HR or 0.79 LPM
353	ELUTE A	0.8	0.0	0.8 HRS		137.8		5.71	5.74	06/08/96	05:03 PM	06/08/96	05:49 PM	36.6 L@ 50.0 CM/HR or 0.79 LPM
354	ELUTE B	0.0	0.0	0.0 HRS		137.8		5.74	5.74	06/08/96	05:49 PM	06/08/96	05:49 PM	0.0 L@ 30.0 CM/HR or 0.47 LPM

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FIG. 12G-1

	OPERATION	PROCESS TIME LINE												CALCULATIONS
		DURATION (HRS.)			REL. TIME SCALE (HRS)			ABS. DAYS		START		FINISH		
		CALC.	A/D	ADJ.	PREP	EXEC.	COMPL.	START	END	DATE	TIME	DATE	TIME	
						15.5				06/03/96	08:00 AM			
355	REGENERATE	0.1	0.0	0.1 HRS			138.0	5.74	5.75	06/08/96	05:49 PM	06/08/96	05:57 PM	12.2 L@ 100.0 CM/HR or 1.58 LPM
356	STORE	0.3	0.0	0.3 HRS			138.2	5.75	5.76	06/08/96	05:57 PM	06/08/96	06:13 PM	24.4 L@ 100.0 CM/HR or 1.58 LPM
357	CIP	1.0	0.0	1.0 HRS			139.2	5.76	5.80	06/08/96	06:13 PM	06/08/96	07:13 PM	
358	SIP	1.0	0.0	1.0 HRS			140.2	5.80	5.84	06/08/96	07:13 PM	06/08/96	08:13 PM	
359	CLEAN UP	1.0	0.0	1.0 HRS			141.2	5.84	5.88	06/08/96	08:13 PM	06/08/96	09:13 PM	
360	SUBTOTAL	6.7		6.7 HRS		137.8								MAX FR 1.58 LPM
361														
362	18 A FLOW DIALYSIS													12.20 SF
363														
364	SET UP	1.0	0.0	1.0 HRS	136.5			5.65	5.69	06/08/96	03:29 PM	06/08/96	04:29 PM	
365	FLUSH	0.7	0.0	0.7 HRS	137.2			5.69	5.72	06/08/96	04:29 PM	06/08/96	05:09 PM	24.4 L@ 3.0 L/SF/Hr or 0.61 LPM
366	PRIME	0.7	0.0	0.7 HRS	137.8			5.72	5.74	06/08/96	05:09 PM	06/08/96	05:49 PM	24.4 L@ 3.0 L/SF/Hr or 0.61 LPM
367	DIALYSIS	1.0	0.0	1.0 HRS		138.8		5.74	5.78	06/08/96	05:49 PM	06/08/96	06:49 PM	36.6 L@ 3.0 L/SF/Hr or 0.61 LPM
368	WASH	0.0	0.0	0.0 HRS		138.8		5.78	5.78	06/08/96	06:49 PM	06/08/96	06:49 PM	0.0 L@ 3.0 L/SF/Hr or 0.61 LPM
369	FLUSH	0.3	0.0	0.3 HRS			139.2	5.78	5.80	06/08/96	06:49 PM	06/08/96	07:09 PM	12.2 L@ 3.0 L/SF/Hr or 0.61 LPM
370	STORE	0.7	0.0	0.7 HRS			139.8	5.80	5.83	06/08/96	07:09 PM	06/08/96	07:49 PM	24.4 L@ 3.0 L/SF/Hr or 0.61 LPM
371	CIP	1.0	0.0	1.0 HRS			140.8	5.83	5.87	06/08/96	07:49 PM	06/08/96	08:49 PM	
372	SIP	1.0	0.0	1.0 HRS			141.8	5.87	5.91	06/08/96	08:49 PM	06/08/96	09:49 PM	
373	CLEAN UP	1.0	0.0	1.0 HRS			142.8	5.91	5.95	06/08/96	09:49 PM	06/08/96	10:49 PM	
374	SUBTOTAL	7.3		7.3 HRS		138.8								MAX FR 0.61 LPM
375														
376	19 A P/A MPLC													7.0 L.CV 0.4 H/D 28.81 CM DIA.
377														
378	EQUILIBRATION	0.5	0.0	0.5 HRS	138.5			5.75	5.77	06/08/96	05:59 PM	06/08/96	06:31 PM	34.8 L@ 100.0 CM/HR or 1.09 LPM
379	LOAD	0.2	0.0	0.2 HRS		139.1		5.78	5.79	06/08/96	06:49 PM	06/08/96	07:03 PM	7.3 L@ 50.0 CM/HR or 0.54 LPM
380	WASH	0.6	0.0	0.6 HRS		139.7		5.79	5.82	06/08/96	07:03 PM	06/08/96	07:41 PM	20.9 L@ 50.0 CM/HR or 0.54 LPM
381	ELUTE A	0.6	0.0	0.6 HRS		140.3		5.82	5.85	06/08/96	07:41 PM	06/08/96	08:20 PM	20.9 L@ 50.0 CM/HR or 0.54 LPM
382	ELUTE B	0.0	0.0	0.0 HRS		140.3		5.85	5.85	06/08/96	08:20 PM	06/08/96	08:20 PM	0.0 L@ 30.0 CM/HR or 0.33 LPM
383	REGENERATE	0.1	0.0	0.1 HRS			140.4	5.85	5.85	06/08/96	08:20 PM	06/08/96	08:26 PM	7.0 L@ 100.0 CM/HR or 1.09 LPM

Sheet 25 of 67
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Title: System And Method For Simulation And Modeling...

FIG. 12G-2

384	STORE	0.2	0.0	0.2 HRS			140.7	5.85	5.86	06/08/96	08:26 PM	06/08/96	08:39 PM	13.9 L@ 100.0 CM/HR or 1.09 LPM
385	CIP	1.0	0.0	1.0 HRS			141.7	5.86	5.90	06/08/96	08:39 PM	06/08/96	09:39 PM	
386	SIP	1.0	0.0	1.0 HRS			142.7	5.90	5.94	06/08/96	09:39 PM	06/08/96	10:39 PM	
387	CLEAN UP	1.0	0.0	1.0 HRS			143.7	5.94	5.99	06/08/96	10:39 PM	06/08/96	11:39 PM	
388	SUBTOTAL	5.4		5.4 HRS		140.3								MAX FR 1.09 LPM
389														
390	20 A FLOW DIALYSIS													2.43 SF
391														
392	SET UP	0.0	0.0	0.0 HRS	139.0			5.79	5.79	06/08/96	07:00 PM	06/08/96	07:00 PM	
393	FLUSH	0.7	0.0	0.7 HRS	139.7			5.79	5.82	06/08/96	07:00 PM	06/08/96	07:40 PM	4.9 L@ 3.0 L/SF/HR or 0.12 LPM
394	PRIME	0.7	0.0	0.7 HRS	140.3			5.82	5.85	06/08/96	07:40 PM	06/08/96	08:20 PM	4.9 L@ 3.0 L/SF/HR or 0.12 LPM
395	DIALYSIS	2.0	0.0	2.0 HRS		142.3		5.85	5.93	06/08/96	08:20 PM	06/08/96	10:20 PM	14.6 L@ 3.0 L/SF/HR or 0.12 LPM
396	WASH	0.0	0.0	0.0 HRS		142.3		5.93	5.93	06/08/96	10:20 PM	06/08/96	10:20 PM	0.0 L@ 3.0 L/SF/HR or 0.12 LPM
397	FLUSH	0.3	0.0	0.3 HRS			142.7	5.93	5.94	06/08/96	10:20 PM	06/08/96	10:40 PM	2.4 L@ 3.0 L/SF/HR or 0.12 LPM
398	STORE	0.7	0.0	0.7 HRS			143.3	5.94	5.97	06/08/96	10:40 PM	06/08/96	11:20 PM	4.9 L@ 3.0 L/SF/HR or 0.12 LPM
399	CIP	0.0	0.0	0.0 HRS			143.3	5.97	5.97	06/08/96	11:20 PM	06/08/96	11:20 PM	
400	SIP	0.0	0.0	0.0 HRS			143.3	5.97	5.97	06/08/96	11:20 PM	06/08/96	11:20 PM	
401	CLEAN UP	0.0	1.0	1.0 HRS			144.3	5.97	6.01	06/08/96	11:20 PM	06/08/96	12:20 AM	
402	SUBTOTAL	4.3		5.3 HRS		142.3								MAX FR 0.12 LPM
403														
404	17 A P/A MPLC													5.3 L.CV 0.4 H/D 26.35 CM DIA.
405														
406	EQUILIBRATION	0.5	0.0	0.5 HRS	142.0			5.89	5.91	06/08/96	09:28 PM	06/08/96	09:57 PM	26.6 L@ 100.0 CM/HR or 0.91 LPM
407	LOAD	0.1	0.0	0.1 HRS		142.4		5.93	5.94	06/08/96	10:20 PM	06/08/96	10:26 PM	2.9 L@ 50.0 CM/HR or 0.45 LPM
408	WASH	0.6	0.0	0.6 HRS		143.0		5.94	5.96	06/08/96	10:26 PM	06/08/96	11:01 PM	16.0 L@ 50.0 CM/HR or 0.45 LPM
409	ELUTE A	0.6	0.0	0.6 HRS		143.6		5.96	5.96	06/08/96	11:01 PM	06/08/96	11:36 PM	16.0 L@ 50.0 CM/HR or 0.45 LPM
410	ELUTE B	0.0	0.0	0.0 HRS		143.6		5.96	5.98	06/08/96	11:36 PM	06/08/96	11:36 PM	0.0 L@ 30.0 CM/HR or 0.27 LPM
411	REGENERATE	0.1	0.0	0.1 HRS			143.7	5.98	5.99	06/08/96	11:36 PM	06/08/96	11:42 PM	5.3 L@ 100.0 CM/HR or 0.91 LPM
412	STORE	0.2	0.0	0.2 HRS			143.9	5.99	6.00	06/08/96	11:42 PM	06/08/96	11:54 PM	10.6 L@ 100.0 CM/HR or 0.91 LPM
413	CIP	0.0	0.0	0.0 HRS			143.9	6.00	6.00	06/08/96	11:54 PM	06/08/96	11:54 PM	
414	SIP	0.0	0.0	0.0 HRS			143.9	6.00	6.00	06/08/96	11:54 PM	06/08/96	11:54 PM	

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FIG. 12H

	OPERATION	PROCESS TIME LINE												CALCULATIONS
		DURATION (HRS.)			REL. TIME SCALE (HRS)			ABS. DAYS		START		FINISH		
		CALC.	A/D	ADJ.	PREP	EXEC.	COMPL.	START	END	DATE	TIME	DATE	TIME	
						15.5				06/03/96	08:00 AM			
415	CLEAN UP	1.0	0.0	1.0 HRS			144.9	6.00	6.04	06/08/96	11:54 PM	06/09/96	12:54 AM	
416	SUBTOTAL	2.1		2.1 HRS		143.6								MAX FR 0.91 LPM
417														
418	22 A STERILE FILTRATION													0.09 SF
419														
420	SET UP	0.5	0.0	0.5 HRS	152.6			6.34	6.36	06/09/96	08:06 AM	06/09/96	06:36 AM	
421	FILTRATION	0.5	0.0	0.5 HRS		144.1		5.98	6.00	06/08/96	11:36 PM	06/09/96	12:06 AM	2.2 L@ 50.0 L/SF/Hr or 0.07 LPM
422	STORAGE	0.5	0.0	0.5 HRS			144.6	6.00	6.03	06/09/96	12:06 AM	06/09/96	12:36 AM	
423	CIP	0.0	0.0	0.0 HRS			144.6	6.03	6.03	06/09/96	12:36 AM	06/09/96	12:36 AM	
424	SIP	0.0	0.0	0.0 HRS			144.6	6.03	6.03	06/09/96	12:36 AM	06/09/96	12:36 AM	
425	CLEAN UP	1.0	0.0	1.0 HRS			145.6	6.03	6.07	06/09/96	12:36 AM	06/09/96	01:36 AM	
426	SUBTOTAL	1.5		1.5 HRS		144.1								MAX FR 0.07 LPM

Sheet 27 of 67
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FIG. 13

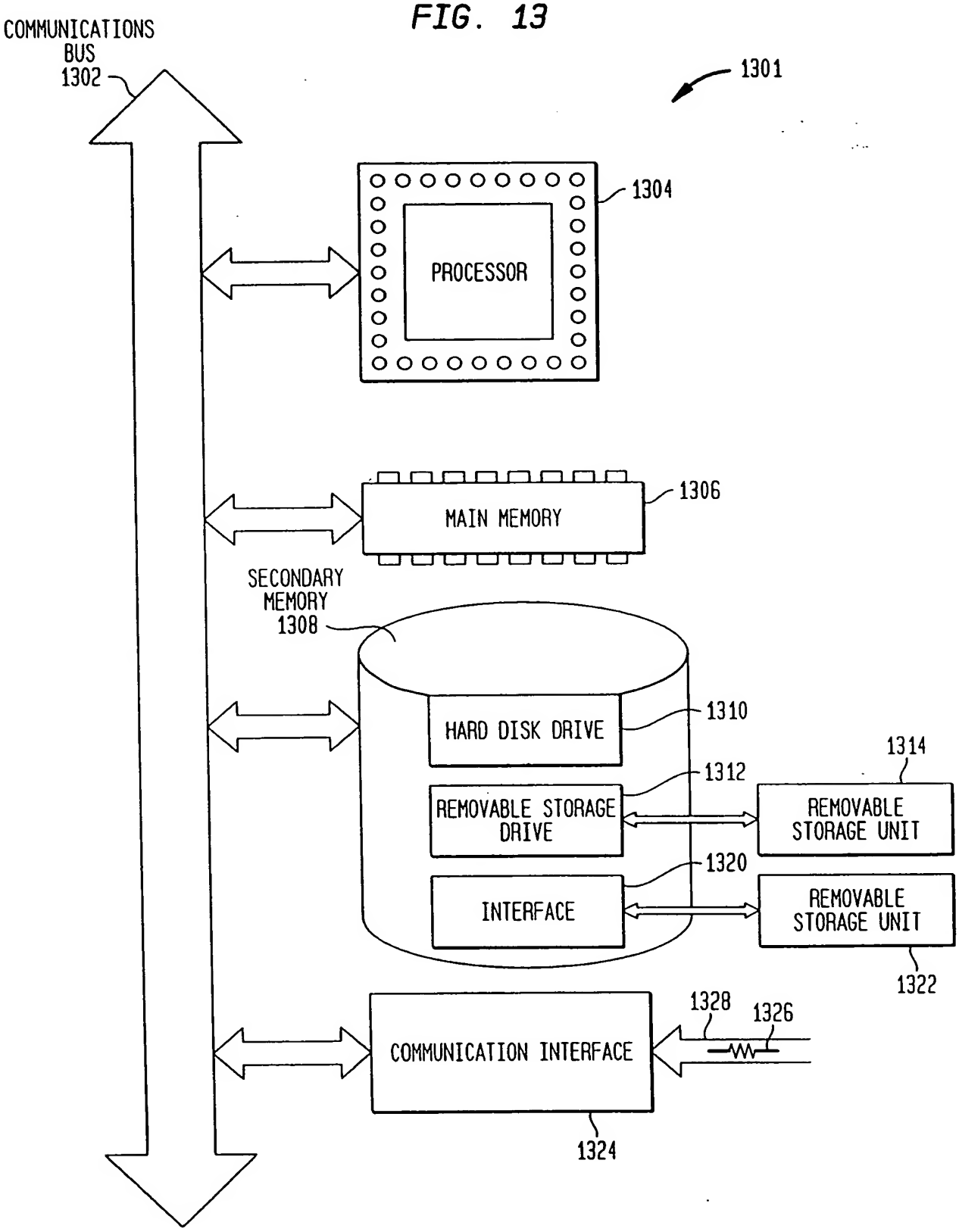

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FIG. 14A

		GROUP 1		
	UNIT OPERATION TYPE	PARAMETER	SOLN.	
T1	INNOCULUM PREP	NUMBER OF FLASKS		2
		MEDIA VOLUME/FLASK		0.25 LITERS
T2	FLASK GROWTH	SCALE UP RATIO		10 FOLD
		MEDIA VOLUME/FLASK		1.25 L
T3	FERMENTATION PRODUCTION	SCALE UP RATIO		10 FOLD
		FERMENTOR WORKING VOLUME	S-101	500 LITERS
		ANTIFOAM A	S-102	1 MI/L
		ANTIFOAM B	S-103	1 MI/L
		BASE	S-104	5 MI/L
		ACID	S-105	5 MI/L
T4	INITIAL SEEDING	NUMBER OF AMPULES		2
		VOLUME PER AMPULE		2 MI
		STARTING CELL DENSITY		300,000 CELLS/MI
		AMPULE SPLIT RATIO		1 VESSELS/AMPULE
		CULTURE VESSEL TYPE		ROLL. BOT.
		FEED VOLUME		100 MI
T5	CULTURE VESSEL SPLIT	VESSEL SPLIT RATIO		2
		NEW VESSEL TYPE		RB
		FEED VOLUME		100 MI
		SERUM CONTENT		2.0% FETAL BOVINE SERUM
T6	SPINNER FLASK SEEDING	FLASK FEED VOLUME		4 LITERS
		VESSEL/FLASK RATIO		0.1 L. CELLS/L FLASK
		uCARRIER DENSITY		5 Gm/LITER
		NUMBER OF PBS WASHES		2
		NUMBER OF MEDIA WASHES		1
		NO. OF MEDIA/SERUM WASHES		2 FBS
T7	BIOSYNTHESIS BIOREACTOR PREPARATION (STIRRED TANK REACTOR)	REACTOR FEED VOLUME		500 LITERS
		SPINNER/REACTOR RATIO		8.3
		uCARRIER DENSITY		5 Gm/LITER
		NUMBER OF PBS WASHES		2
		NUMBER OF MEDIA WASHES		1
		NO. OF MEDIA/SERUM WASHES		2
T8	BIOSYNTHESIS BIOREACTOR PREPARATION (HOLLOW FIBER REACTOR)	REACTOR FEED VOLUME		100 LITERS
		NUMBER OF PBS WASHES		2
		NUMBER OF MEDIA WASHES		2
		NO. OF MEDIA/SERUM WASHES		2
		SERUM CONTENT		2.0% FETAL BOVINE SERUM
T9	BIOSYNTHESIS BIOREACTOR PREPARATION (FLUIDIZED BED REACTOR)	REACTOR FEED VOLUME		LITERS
		uCARRIER DENSITY		Gms/L
		NUMBER OF PBS WASHES		
		NUMBER OF MEDIA WASHES		
		NO. OF MEDIA/SERUM WASHES		
		SERUM CONTENT		
T10	INITIAL SEEDING	NUMBER OF AMPULES		2
		VOLUME PER AMPULE		2 MI
		STARTING CELL DENSITY		300,000 CELLS/MI
		AMPULE SPLIT RATIO		1 VESSELS/AMPULE

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FIG. 14B

GROUP 2			GROUP 3		
PARAMETER	SOLN.		PARAMETER	SOLN.	
TEMPERATURE		37 C	FINAL OD		12
AGITATION		200 RPM			
DURATION		18 HOURS			
TEMPERATURE		37 C	FINAL OD		12
AGITATION		200 HOURS			
DURATION		16 RPM			
GROWTH TEMPERATURE		37 HOURS	FINAL OD		12
AGITATION		1 HP/100L	DRY CELL MASS		9.96 Gas TDCM/L
SPARGE RATE		1.5 VVM	PRODUCT CONCENTRATION		0.3 Gas PRODUCT/L
BACK PRESSURE		5 PSIG	CIP		Y
TOTAL DURATION		21 HRS			
SERUM CONTENT		2.0% FETAL BOVINE SERUM	AMPLIFICATION FACTOR		100%
FEED RATE		1 FEED PER VESSEL PER			
		2 DAYS			
DAYS TO CONFLUENCE		2 DAYS			
FEED RATE		1 FEED PER VESSEL PER	AMPLIFICATION FACTOR		100%
		2 DAYS			
DAYS TO CONFLUENCE		2 DAYS			
SERUM CONTENT		2.0% FETAL BOVINE SERUM	AMPLIFICATION FACTOR		100%
FEED RATE		1 FEED PER VESSEL PER			
		2 DAYS			
DAYS TO CONFLUENCE		2 DAYS			
SERUM CONTENT		2.0% FETAL BOVINE SERUM	PRODUCT CONCENTRATION		2500% Mg PROD/L
FEED RATE		1 FEED PER VESSEL PER	TOTAL PROTEIN CONCEN.		0.125 Mg TP/MI
		2 DAYS			
DAYS TO CONFLUENCE		10 DAYS			
SERUM FREE MEDIA WASHES		2			
NUMBER OF REACTORS		1	HARVEST VOLUME		500% LITERS
FEED RATE		1 FEED PER VESSEL PER	PRODUCT CONCENTRATION		25 Mg PROD/L
		1 DAYS	TOTAL PROTEIN CONCEN.		0.125 Mg TP/MI
DAYS TO CONFLUENCE		10 DAYS			
NUMBER OF REACTORS		1	PRODUCT CONCENTRATION		2500% Mg PROD/L
FEED RATE		1 FEED PER VESSEL PER	TOTAL PROTEIN CONCEN.		0.125 Mg TP/MI
		1 DAYS			
DAYS TO CONFLUENCE		10 DAYS			
SERUM CONTENT		2.0% FETAL BOVINE SERUM	AMPLIFICATION FACTOR		100%
FEED RATE		1 FEED PER VESSEL PER			
		2 DAYS			
DAYS TO CONFLUENCE		2 DAYS			

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Title: System And Method For Simulation And Modeling...

FIG. 15A

	UNIT OPERATION TYPE	GROUP 1		
		PARAMETER	SOLN.	
		CULTURE VESSEL TYPE		ROLL. BOT.
		FEED VOLUME		100 MI
T11	CULTURE VESSEL SPLIT	VESSEL SPLIT RATIO		2
		NEW VESSEL TYPE		RB
		FEED VOLUME		100 MI
		SERUM CONTENT		2.0% FETAL BOVINE SERUM
T12	SPINNER FLASK SPLIT	FLASK FEED VOLUME		4 LITERS
		VESSEL/FLASK RATIO		0.1 L CELLS/L FLASK
		uCARRIER DENSITY		5 Gm/LITER
		NUMBER OF PBS WASHES		2
		NUMBER OF MEDIA WASHES		1
		NO. OF MEDIA/SERUM WASHES		2
T13	BIOSYNTHESIS BIOREACTOR PREPARATION (STIRRED TANK REACTOR)	REACTOR FEED VOLUME		500 LITERS
		SPINNER/REACTOR RATIO		8.3
		uCARRIER DENSITY		5 Gm/LITER
		NUMBER OF PBS WASHES		2
		NUMBER OF MEDIA WASHES		1
		NO. OF MEDIA/SERUM WASHES		2
T14	BIOSYNTHESIS BIOREACTOR PREPARATION (FLUIDIZED BED REACTOR)	REACTOR FEED VOLUME		LITERS
		uCARRIER DENSITY		GmS/L
		NUMBER OF PBS WASHES		
		NUMBER OF MEDIA WASHES		
		NO. OF MEDIA/SERUM WASHES		
		SERUM CONTENT		
T15	INITIAL COUPLING	FLASK FEED VOLUME		4 LITERS
		VESSEL/FLASK RATIO		0.1 L CELLS/L FLASK
		uCARRIER DENSITY		5 Gm/LITER
		NUMBER OF PBS WASHES		2
		NUMBER OF MEDIA WASHES		1
		NO. OF MEDIA/SERUM WASHES		2 FBS
T16	ADDITIONAL COUPLING	REACTOR FEED VOLUME		500 LITERS
		SPINNER/REACTOR RATIO		8.3
		uCARRIER DENSITY		5 Gm/LITER
		NUMBER OF PBS WASHES		2
		NUMBER OF MEDIA WASHES		1
		NO. OF MEDIA/SERUM WASHES		2
T17	PEPTIDE CLEAVAGE	REACTOR FEED VOLUME		100 LITERS
		NUMBER OF PBS WASHES		2
		NUMBER OF MEDIA WASHES		2
		NO. OF MEDIA/SERUM WASHES		2
		SERUM CONTENT		2.0% FETAL BOVINE SERUM
T18	TISSUE THAWING	CRUDE PRODUCT YEILD		25 Gm CRUDE PROD./Kg TISSUE
		ENVIRONMENTAL TEMPERATURE		25 C
		THAW DURATION		16 HOURS
T19	HOMOGENIZATION	CRUDE PRODUCT YEILD		25 Gm CRUDE PROD./Kg TISSUE
		LIQUID/SOLID RATIO		10 L SOLUTION/KG TISSUE
		HOMMOGENIZATION TEMP.		4 C
		HOMMOGENIZER TYPE		RS
		ENERGY INPUT		200 HP/100L/HR
		DURATION		4 HOURS
T20	LIQUID THAWING			

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FIG. 15B

GROUP 2			GROUP 3		
PARAMETER	SOLN.		PARAMETER	SOLN.	
PBS WASHES TRYPSIN WASH		200 MI 100 MI			
FEED RATE DAYS TO CONFLUENCE PBS WASHES TRYPSIN WASH		1 FEED PER VESSEL PER 2 DAYS 2 DAYS 200 MI 100 MI	AMPLIFICATION FACTOR		100%
SERUM CONTENT FEED RATE DAYS TO CONFLUENCE		2.0% FETAL BOVINE SERUM 1 FEED PER VESSEL PER 2 DAYS 2 DAYS	AMPLIFICATION FACTOR		100%
SERUM CONTENT FEED RATE DAYS TO CONFLUENCE SERUM FREE MEDIA WASHES		2.0% FETAL BOVINE SERUM 1 FEED PER VESSEL PER 2 DAYS 10 DAYS 2	PRODUCT CONCENTRATION TOTAL PROTEIN CONCEN.		2500% Mg PROD/L 0.125 Mg TP/MI
NUMBER OF REACTORS FEED RATE DAYS TO CONFLUENCE		1 1 FEED PER VESSEL PER 1 DAYS 10 DAYS	PRODUCT CONCENTRATION TOTAL PROTEIN CONCEN.		2500% Mg PROD/L 0.125 Mg TP/MI
SERUM CONTENT FEED RATE DAYS TO CONFLUENCE		2.0% FETAL BOVINE SERUM 1 FEED PER VESSEL PER 2 DAYS 2 DAYS	AMPLIFICATION FACTOR		100%
SERUM CONTENT FEED RATE DAYS TO CONFLUENCE SERUM FREE MEDIA WASHES		2.0% FETAL BOVINE SERUM 1 FEED PER VESSEL PER 2 DAYS 10 DAYS 2	PRODUCT CONCENTRATION TOTAL PROTEIN CONCEN.		2500% Mg PROD/L 0.125 Mg TP/MI
NUMBER OF REACTORS FEED RATE DAYS TO CONFLUENCE		1 1 FEED PER VESSEL PER 1 DAYS 10 DAYS	HARVEST VOLUME PRODUCT CONCENTRATION TOTAL PROTEIN CONCEN.		500% LITERS 25 Mg PROD/L 0.125 Mg TP/MI
CONTAMINANT PROTEIN CONC.		100 Ga/L	TEMPERATURE REGULATION CIP SIP		Y Y Y
CONTAMINANT PROTEIN CONC.		100 Ga/L	TEMPERATURE REGULATION CIP SIP		Y Y Y
			AMPLIFICATION FACTOR		100%

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FIG. 16A

	UNIT OPERATION TYPE	GROUP 1		
		PARAMETER	SOLN.	
T21	PRODUCT Ppt BY SOLIDS	REAGENT CONCENTRATION		1 M
T22	PRODUCT Ppt BY LIQUIDS	REAGENT CONCENTRATION		1 M
T23	CONTAINMENT Ppt BY SOLIDS	REAGENT CONCENTRATION		1 M
T24	CONTAINMENT Ppt BY LIQUIDS	REAGENT CONCENTRATION		1 M
T25	SOLIDS HARVEST TANGENTIAL FLOW MF	POROSITY AVERAGE FLUX RATE TOTAL THROUGHPUT FILTRATION TIME		0.2 MICRON 11 L/SF/HR AT 40 PSIG AT 4 C 400 LITERS/SF 1 HR
T26	CONTINUOUS CENTRIFUGATION SOLIDS HARVEST	SYSTEM VOID VOLUME		5 LITERS
T27	CONTINUOUS CENTRIFUGATION SUPERNATANT HARVEST	SYSTEM VOID VOLUME		6 LITERS
T28	DILUTION	SYSTEM VOID VOLUME		6 LITERS
T29	BATCH CENTRIFUGATION SOLIDS HARVEST	SYSTEM VOID VOLUME		6 LITERS

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Title: System And Method For Simulation And Modeling...

FIG. 16B

GROUP 2			GROUP 3		
PARAMETER	SOLN.		PARAMETER	SOLN.	
Kgms OF REAGENT/LITERS PRODUCT		0.25 Kg/L	STEP RECOVERY OF PRODUCT		95%
TEMPERATURE		4 C	STEP RECOVERY OF T.P.		95%
ADDITION TIME		0.5 HOURS			
ADDITIONAL MIX TIME		2 HOURS	TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
LITERS REAGENT/LITERS PRODUCT		0.25 L/L	STEP RECOVERY OF PRODUCT		95%
TEMPERATURE		4 C	STEP RECOVERY OF T.P.		95%
ADDITION TIME		0.5 HOURS			
ADDITIONAL MIX TIME		2 HOURS	TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
Kgms OF REAGENT/LITERS PRODUCT		0.25 Kg/L	STEP RECOVERY OF PRODUCT		95%
TEMPERATURE		4 C	STEP RECOVERY OF T.P.		95%
ADDITION TIME		0.5 HOURS			
ADDITIONAL MIX TIME		2 HOURS	TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
LITERS REAGENT/LITERS PRODUCT		0.25 L/L	STEP RECOVERY OF PRODUCT		95%
TEMPERATURE		4 C	STEP RECOVERY OF T.P.		95%
ADDITION TIME		0.5 HOURS			
ADDITIONAL MIX TIME		2 HOURS	TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
FLUSH		2 L/SF	STEP RECOVERY OF PRODUCT		95%
PRIME		2 L/SF	STEP RECOVERY OF T.P.		95%
CONCENTRATION FACTOR		10 FOLD			
WASH		0.5 L/SF	TEMPERATURE REGULATION		Y
REGENERATE		1 L/SF	CIP		Y
STORE		2 L/SF	SIP		Y
RCF		10,000 X G	STEP RECOVERY OF PRODUCT		95%
TIME		60 MINUTES	STEP RECOVERY OF T.P.		95%
VOLUME REDUCTION		30 X VOL. REDUCTION			
WASH VOLUME		0.2 X SYSTEM VOID VOLUME	TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
RCF		10,000 X G	STEP RECOVERY OF PRODUCT		85%
TIME		30 MINUTES	STEP RECOVERY OF T.P.		0.3
VOLUME REDUCTION		0.062 VOL. REDUCTION			
WASH VOLUME		1.5 X SYSTEM VOID VOLUME	TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
RCF		10,000 X G	STEP RECOVERY OF PRODUCT		95%
TIME		30 MINUTES	STEP RECOVERY OF T.P.		0.95
VOLUME REDUCTION		16 X VOL. REDUCTION			
WASH VOLUME		1.5 X SYSTEM VOID VOLUME	TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
RCF		10,000 X G	STEP RECOVERY OF PRODUCT		95%
TIME		30 MINUTES	STEP RECOVERY OF T.P.		0.95

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FIG. 17A

	UNIT OPERATION TYPE	GROUP 1		
		PARAMETER	SOLN.	
T30	BATCH CENTRIFUGATION SUPERNATANT HARVEST	SYSTEM VOID VOLUME		6 LITERS
T31	CELL DISRUPTION HIGH PRESS. HOMOGEN.	PRODUCT TEMPERATURE UTILITY TEMPERATURE VOID VOLUME		8 C 2 C 5 LITERS
T32	CELL DISRUPTION BEAD MILL	NUMBER OF PASSES BEAD SIZE VOID VOLUME FLOW RATE		2 0.5 LPM
T33	CELL DISRUPTION CHEMICAL LYSIS	REAGENT TEMPERATURE EXPOSURE TIME		0.5 M NaOH 4 C 2 HOURS
T34	MICROFILTRATION TANGENTIAL FLOW	POROSITY AVERAGE FLUX RATE TOTAL THROUGHPUT FILTRATION TIME		0.2 MICRON 50 L/SF/HR AT 40 PSIG AT 4 C 400 LITERS/SF 2 HR
T35	MICROFILTRATION DEAD END	POROSITY AVERAGE FLUX RATE TOTAL THROUGHPUT FILTRATION TIME		0.2 MICRON 50 L/SF/HR AT 40 PSIG AT 4 C 400 LITERS/SF 0.5 HR
T36	ULTRAFILTRATION CONCENTRATION/DILUTION	POROSITY AVERAGE FLUX RATE CONCENTRATION TIME		60 K NMWL 3 L/SF/HR AT 40 PSIG AT 4 C 2 HR.
T37	ULTRAFILTRATION FLOW DIALYSIS	POROSITY AVERAGE FLUX RATE		60 K NMWL 3 L/SF/HR AT 40 PSIG AT 4 C

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FIG. 17B

GROUP 2			GROUP 3		
PARAMETER	SOLN.		PARAMETER	SOLN.	
VOLUME REDUCTION		16 X VOL. REDUCTION			
WASH VOLUME		1.5 X SYSTEM VOID VOLUME	TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
RCF		10000 X G	STEP RECOVERY OF PRODUCT		95%
TIME		30 MINUTES	STEP RECOVERY OF T.P.		0.95
VOLUME REDUCTION		16 X VOL. REDUCTION			
WASH VOLUME		1.5 X SYSTEM VOID VOLUME	TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
NUMBER OF PASSES		6 TIMES	RINSE		500% VOID VOLUMES
PRESSURE		12,000 PSI	STEP RECOVERY OF PRODUCT		95%
FLOW RATE		5 LPM	STEP RECOVERY OF T.P.		95%
TEMPERATURE INCREASE		1.8 DEGREES C/1,000 PSI	TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
			STEP RECOVERY OF PRODUCT		95%
			STEP RECOVERY OF T.P.		
			TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
LITERS REAGENT/Gm PRODUCT		0.4 L/Gm	STEP RECOVERY OF PRODUCT		95%
TITRATION		0 MI/LITER	STEP RECOVERY OF T.P.		
			TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
FLUSH		2.00 L/SF	STEP RECOVERY OF PRODUCT		95%
PRIME		2.00 L/SF	STEP RECOVERY OF T.P.		95%
WASH		0.50 L/SF			
SOLIDS		0.30% OF PRODUCT SOLUTION	TEMPERATURE REGULATION		Y
REGENERATE		1.00 L/SF	CIP		Y
STORE		2.00 L/SF	SIP		Y
FLUSH		0 L/SF	STEP RECOVERY OF PRODUCT		95%
PRIME		0 L/SF	STEP RECOVERY OF T.P.		0.95
WASH		0.5 L/SF			
SOLIDS		0.003 OF PRODUCT SOLUTION	TEMPERATURE REGULATION		N
REGENERATE		1 L/SF	CIP		N
STORE		2 L/SF	SIP		N
FLUSH		2.00 L/SF	STORE		2.00 L/SF
PRIME		2.00 L/SF	STEP RECOVERY OF PRODUCT		95%
WASH		0.50 L/SF	STEP RECOVERY OF T.P.		95%
DILUTE CONCENTRATE		10.0 FOLD	TEMPERATURE REGULATION		Y
SOLIDS		0.30% OF PRODUCT SOLUTION	CIP		Y
REGENERATE		1.00 L/SF	SIP		Y
FLUSH		2 L/SF	STORE		200% L/SF
PRIME		2.00 L/SF	STEP RECOVERY OF PRODUCT		95%
DIALYSIS BUFFER		5.0 X FEED STREAM VOLUME	STEP RECOVERY OF T.P.		95%
WASH		0.50 L/SF	TEMPERATURE REGULATION		Y

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FIG. 18A

	UNIT OPERATION TYPE	GROUP 1		
		PARAMETER	SOLN.	
		DIALYSIS TIME		2 HR
T38	PROD. ADS. CHROMATOGRAPHY HPLC	COLUMN CAPACITY COLUMN OVERSIZE FACTOR COLUMN ASPECT RATIO MAX. LINEAR VELOCITY		10 Mg PROD./MI OF PACKING 1.5 FOLD 0.37 H/D 100 Cm/HR AT 45 PSIG AND 4 C
T39	PROD. ADS. CHROMATOGRAPHY HPLC	COLUMN CAPACITY COLUMN OVERSIZE FACTOR COLUMN ASPECT RATIO MAX. LINEAR VELOCITY		10 Mg PROD./MI OF PACKING 1.5 FOLD 0.37 H/D 100 Cm/HR AT 45 PSIG AND 4 C
T40	PROD. ADS. CHROMATOGRAPHY LPLC	COLUMN CAPACITY COLUMN OVERSIZE FACTOR COLUMN ASPECT RATIO MAX. LINEAR VELOCITY		10 Mg PROD./MI OF PACKING 1.5 FOLD 0.37 H/D 100 Cm/HR AT 45 PSIG AND 4 C
T41	CONT. ADS. CHROMATOGRAPHY HPLC	COLUMN CAPACITY COLUMN OVERSIZE FACTOR COLUMN ASPECT RATIO MAX. LINEAR VELOCITY		30 Mg CONT./MI OF PACKING 1.5 FOLD 0.37 H/D 100 Cm/HR AT 45 PSIG AND 4 C
T42	CONT. ADS. CHROMATOGRAPHY HPLC	COLUMN CAPACITY COLUMN OVERSIZE FACTOR COLUMN ASPECT RATIO MAX. LINEAR VELOCITY		10 Mg CONT./MI OF PACKING 1.5 FOLD 0.37 H/D 100 Cm/HR AT 45 PSIG AND 400% C
T43	CONT. ADS. CHROMATOGRAPHY LPLC	COLUMN CAPACITY COLUMN OVERSIZE FACTOR COLUMN ASPECT RATIO MAX. LINEAR VELOCITY		10 Mg CONT./MI OF PACKING 1.5 FOLD 0.37 H/D 100 Cm/HR AT 45 PSIG AND 4 C
T44	SIZE EXCL. CHROMATOGRAPHY HPLC	LOAD CAPACITY LENGTH MAX. LINEAR VELOCITY VOID VOLUME		5% OF TOTAL COLUMN VOLUME 100 Cm 100 Cm/HR AT 45 PSIG AND 4 C 25% COLUMN VOLUME
T45	SIZE EXCL. CHROMATOGRAPHY HPLC	LOAD CAPACITY LENGTH MAX. LINEAR VELOCITY VOID VOLUME		5% OF TOTAL COLUMN VOLUME 100 Cm 100 Cm/HR AT 45 PSIG AND 4 C 25% COLUMN VOLUME

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FIG. 18B

GROUP 2			GROUP 3		
PARAMETER	SOLN.		PARAMETER	SOLN.	
SOLIDS		0.30% OF PRODUCT SOLUTION	CIP		Y
REGENERATE		1.00 L/SF	SIP		Y
COLUMN EQUILIBRATION		5 COLUMN VOLUMES	PROD. ELUTION VOLUME		80%
COLUMN WASH		3 COLUMN VOLUMES	STEP RECOVERY OF PRODUCT		95%
COLUMN ELUTE A		3 COLUMN VOLUMES	STEP RECOVERY OF T.P.		95%
COLUMN ELUTE B		0 COLUMN VOLUMES	TEMPERATURE REGULATION		N
COLUMN REGENERATE		1 COLUMN VOLUMES	CIP		Y
COLUMN STORE		2 COLUMN VOLUMES	SIP		Y
COLUMN EQUILIBRATION		5 COLUMN VOLUMES	PROD. ELUTION VOLUME		80%
COLUMN WASH		3 COLUMN VOLUMES	STEP RECOVERY OF PRODUCT		95%
COLUMN ELUTE A		3 COLUMN VOLUMES	STEP RECOVERY OF T.P.		95%
COLUMN ELUTE B		0 COLUMN VOLUMES	TEMPERATURE REGULATION		N
COLUMN REGENERATE		1 COLUMN VOLUMES	CIP		Y
COLUMN STORE		2 COLUMN VOLUMES	SIP		Y
COLUMN EQUILIBRATION		5 COLUMN VOLUMES	PROD. ELUTION VOLUME		42%
COLUMN WASH		3 COLUMN VOLUMES	STEP RECOVERY OF PRODUCT		95%
COLUMN ELUTE A		3 COLUMN VOLUMES	STEP RECOVERY OF T.P.		95%
COLUMN ELUTE B		2 COLUMN VOLUMES	TEMPERATURE REGULATION		N
COLUMN REGENERATE		1 COLUMN VOLUMES	CIP		Y
COLUMN STORE		2 COLUMN VOLUMES	SIP		Y
COLUMN EQUILIBRATION		5 COLUMN VOLUMES	PROD. ELUTION VOLUME		42%
COLUMN WASH		3 COLUMN VOLUMES	STEP RECOVERY OF PRODUCT		95%
COLUMN ELUTE A		3 COLUMN VOLUMES	STEP RECOVERY OF T.P.		95%
COLUMN ELUTE B		2 COLUMN VOLUMES	TEMPERATURE REGULATION		N
COLUMN REGENERATE		1 COLUMN VOLUMES	CIP		Y
COLUMN STORE		2 COLUMN VOLUMES	SIP		Y
COLUMN EQUILIBRATION		5 COLUMN VOLUMES	PROD. ELUTION VOLUME		42%
COLUMN WASH		3 COLUMN VOLUMES	STEP RECOVERY OF PRODUCT		95%
COLUMN ELUTE A		3 COLUMN VOLUMES	STEP RECOVERY OF T.P.		95%
COLUMN ELUTE B		2 COLUMN VOLUMES	TEMPERATURE REGULATION		N
COLUMN REGENERATE		1 COLUMN VOLUMES	CIP		Y
COLUMN STORE		2 COLUMN VOLUMES	SIP		Y
COLUMN EQUILIBRATION		5 COLUMN VOLUMES	PROD. ELUTION VOLUME		42% COLUMNS VOLUMES
COLUMN WASH		3 COLUMN VOLUMES	STEP RECOVERY OF PRODUCT		95%
COLUMN ELUTE A		3 COLUMN VOLUMES	STEP RECOVERY OF T.P.		95%
COLUMN ELUTE B		2 COLUMN VOLUMES	TEMPERATURE REGULATION		N
COLUMN REGENERATE		1 COLUMN VOLUMES	CIP		Y
COLUMN STORE		2 COLUMN VOLUMES	SIP		Y
COLUMN EQUILIBRATION		4 COLUMN VOLUMES	PROD. ELUTION VOLUME		42% COLUMNS VOLUMES
COLUMN WASH		1 COLUMN VOLUMES	STEP RECOVERY OF PRODUCT		95%
COLUMN REGENERATE		1 COLUMN VOLUMES	STEP RECOVERY OF T.P.		95%
COLUMN STORE		2 COLUMN VOLUMES	TEMPERATURE REGULATION		N
			CIP		Y
			SIP		Y
COLUMN EQUILIBRATION		4 COLUMN VOLUMES	PROD. ELUTION VOLUME		42% COLUMNS VOLUMES
COLUMN WASH		1 COLUMN VOLUMES	STEP RECOVERY OF PRODUCT		95%
COLUMN REGENERATE		1 COLUMN VOLUMES	STEP RECOVERY OF T.P.		95%
COLUMN STORE		2 COLUMN VOLUMES	TEMPERATURE REGULATION		N
			CIP		Y
			SIP		Y

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FIG. 19A

	UNIT OPERATION TYPE	GROUP 1		
		PARAMETER	SOLN.	
T46	SIZE EXCL. CHROMATOGRAPHY LPLC	LOAD CAPACITY		5% OF TOTAL COLUMN VOLUME
		LENGTH		100 Cm
		MAX. LINEAR VELOCITY		100 Cm/HR AT
				45 PSIG AND
				4 C
		VOID VOLUME		25% COLUMN VOLUME
T47	DILUTION	DILUTION FACTOR		3 LITERS/LITER
T48	RESOLUBILIZATION	REGEANT/PRODUCT RATIO		0 L/Kg PRODUCT
		DISSOLUTION TIME		0.50 HOURS
		ADDITIONAL MIX TIME		0.50 HOURS
T49	ENZYMATIC MODIFICTAION	ENZYME TO PRODUCT RATIO		0.084 LITERS OF ENZYME STOCK PER LITER OF START. PROC. VOL.
		ENZYME CONCENTRATION		2 Mg/Ml
		REACTION TEMP.		37 DEGREES C
		REACTION DURATION		30 MINUTES
				100%
T50	LYOPHILIZATION	PRODUCT CAPACITY/LOAD		8 UNITS
		PRODUCT UNIT SIZE		100 GRAMS/UNIT
T51	HEAT EXCHANGE	PROCESS INITIAL TEMP		98.6 DEGREES C
		PROCESS FINAL TEMP		39.2 DEGREES C
		UTILITY INITIAL TEMP		34 DEGREES C
		UTILITY FINAL TEMP		5 DEGREES C
		PROCESS SPECIFIC HEAT		38.6 K BTU/HR
		DESIGN TYPE (P,T,C)		P
T52	STORAGE			
T53	FERMENTATION SEED	SCALE UP RATIO		10 FOLD
		FERMENTOR WORKING VOLUME		50 LITERS
		ANTIFOAM A		1 Ml/L
		ANTIFOAM B		1 Ml/L
		BASE		5 Ml/L
		ACID		5 Ml/L
T54	INITIAL SEEDING	FLASK FEED VOLUME		12 LITERS
		SPINNER SPLIT RATIO		4

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FIG. 19B

GROUP 2			GROUP 3		
PARAMETER	SOLN.		PARAMETER	SOLN.	
COLUMN EQUILIBRATION		4 COLUMN VOLUMES	PROD. ELUTION VOLUME		42% COLUMN VOLUMES
COLUMN WASH		1 COLUMN VOLUMES	STEP RECOVERY OF PRODUCT		95%
COLUMN REGENERATE		1 COLUMN VOLUMES	STEP RECOVERY OF T.P.		95%
COLUMN STORE		2 COLUMN VOLUMES	TEMPERATURE REGULATION		N
			CIP		Y
			SIP		Y
DILUTION TIME		0.5 HOURS	STEP RECOVERY OF PRODUCT		95%
ADDITIONAL MIX TIME		1 HOURS	STEP RECOVERY OF T.P.		95%
			TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
REGEANT 1		WATER	STEP RECOVERY OF PRODUCT		95%
CONCENTRATION		DIST.	STEP RECOVERY OF T.P.		95%
			TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
TITRATION SOLUTION-1		0.067 L/L PROCESS	STEP RECOVERY OF PRODUCT		95%
TITRATION SOLUTION-2		0.02 L/L PROCESS	STEP RECOVERY OF T.P.		95%
NEUTRALIZATION		0.57 L/L PROCESS			
			TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
LYOPHILIZATION TIME		18 HOURS	STEP RECOVERY OF PRODUCT		95%
PRODUCT WEIGHT REDUCTION		0.95	STEP RECOVERY OF T.P.		95%
					Y
			CIP		Y
			SIP		Y
EXPOSURE TIME		1 HOURS	STEP RECOVERY OF PRODUCT		100%
			STEP RECOVERY OF T.P.		100%
			TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
			STEP RECOVERY OF PRODUCT		95%
			STEP RECOVERY OF T.P.		95%
			TEMPERATURE REGULATION		Y
			CIP		Y
			SIP		Y
GROWTH TEMPERATURE		37 HOURS	FINAL OD		12
AGITATION		1 HP/100L	CIP		
SPARGE RATE		1.5 VVM			
BACK PRESSURE		5 PSIG			Y
TOTAL DURATION		21 HRS			
SERUM CONTENT		2% FBS	AMPLIFICATION FACTOR		1
FEED RATE		1 FEED PER VESSEL PER			

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FIG. 20A

	UNIT OPERATION TYPE	GROUP 1		
		PARAMETER	SOLN.	
		uCARRIER DENSITY		5 Gm/LITER
		NUMBER OF PBS WASHES		2
		NUMBER OF MEDIA WASHES		1
		NO. OF MEDIA/SERUM WASHES		2 FBS
T55	CULTURE VESSEL SPLIT	FLASK FEED VOLUME		12 LITERS
		SPINNER SPLIT RATIO		4
		uCARRIER DENSITY		5 Gm/LITER
		NUMBER OF PBS WASHES		2
		NUMBER OF MEDIA WASHES		1
		NO. OF MEDIA/SERUM WASHES		2 FBS
T56	CULTURE FLASK SPLIT			
T57	STIRRED TANK REACTOR			
T58	FLUIDIZED BED REACTOR	PROCESS INITIAL TEMP		37 DEGREES C
		PROCESS FINAL TEMP		4 DEGREES C
		UTILITY INITIAL TEMP		2 DEGREES C
		UTILITY FINAL TEMP		5 DEGREES C
		PROCESS SPECIFIC HEAT		12 K BTU/HR
		DESIGN TYPE (P,T,C)		P
T59	LIQUID/LIQUID EXTRACTION	LIQUID/LIQUID RATIO		1 L EXTRACTION/L PRODUCT
		EXTRACTION TEMPERATURE		4 C
		ADDITION DURATION		0.5 HOURS
		ADDITIONAL MIX. DURATION		4 HOURS
		MIX ENERGY		0.3 HP/100L
T60	SOLID/LIQUID EXTRACTION	LIQUID/LIQUID RATIO		1 L EXTRACTION/L PRODUCT
		EXTRACTION TEMPERATURE		4 C
		DURATION		4 HOURS
		MIX ENERGY		0.3 HP/100 L

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FIG. 20B

GROUP 2			GROUP 3		
PARAMETER	SOLN.		PARAMETER	SOLN.	
DAYS TO CONFLUENCE		2 DAYS 2 DAYS			
SERUM CONTENT FEED RATE DAYS TO CONFLUENCE		2% FBS 1 FEED PER VESSEL PER 2 DAYS 2 DAYS	AMPLIFICATION FACTOR		1
			STEP RECOVERY OF PRODUCT STEP RECOVERY OF T.P. CIP SIP		0.95 95% Y Y Y
EXPOSURE TIME		50% HOURS	STEP RECOVERY OF PRODUCT STEP RECOVERY OF T.P. TEMPERATURE REGULATION CIP SIP		0.95 100% Y Y Y
PHASE SEPARATION TIME PRODUCT PHASE (TOP/BOTTOM) HARVEST TIME		1600% HOURS TOP 0.5 HOURS	STEP RECOVERY OF PRODUCT STEP RECOVERY OF T.P. TEMPERATURE REGULATION CIP SIP		0.9 50% Y Y Y
PHASE SEPARATION TIME PRODUCT PHASE (TOP/BOTTOM) HARVEST TIME		1600% HOURS TOP 0.5 HOURS	STEP RECOVERY OF PRODUCT STEP RECOVERY OF T.P. TEMPERATURE REGULATION CIP SIP		0.9 50% Y Y Y

UOP Seq. No.	Code	Unit Operation Type	Process Design Cycles									
			Unit Op		Unit Op Cluster				Batch			
				Offset (Hrs)		UnOp Start	UnOp End	Offset (Hrs)		UnOp Start	UnOp End	Offset (Hrs)
1	68	STR-Suspension Production	1	0	1			0	1			0
2	74	Harvest/Feed-Suspension Production	3	24	1			0	20	2	4	72
3	34	Tangential Flow-Clarification	1	0	1			0	20	2	4	72
4	47	Dilution	1	0	1			0	20	2	4	72
5	99	End										

2102 2104 2106 2108 2110 2112 2114 2116 2118 2120 2122 2124 2126

FIG. 21

0303-84.vsd/1

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UOP Seq. No.	Code	Unit Operation Type	Process Design Cycles									
			Unit Op		Unit Op Cluster				Batch			
				Offset (Hrs)		UnOp Start	UnOp End	Offset (Hrs)		UnOp Start	UnOp End	Offset (Hrs)
10301	87	Pool	1		1				1			
10302	51	Heat Exchange	1		1				1			
10303	26	Cont. Centrifugation - Solids Harvest	1		1				1			
10304	48	Resolubilization	1		1				1			
10305	61	Inlet Heat Exchange	1		3	5	7		1			
10306	31	High Pressure Homogenization	1		3	5	7	S	1			
10307	51	Outlet Heat Exchange	1		3	5	7	S	1			
10308	29	Batch Centrifugation - Solids Harvest	1		1				1			
10309	29	Dilution - IB Wash	1		2	9	10		1			
10310	29	Batch Centrifugation - Solids Harvest	1		2	9	10		1			
10311	63	Storage	1		1				1			
10312	99	End	1		1				1			

2202 2204 2206 2208 2210 2212 2214 2216 2218 2220 2222 2224 2226

FIG. 22

0303-84.vsd/2

Sheet 44 of 67
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OPERATION	CALCULATIONS				
1.1.1.1 T76 MUTI-STAGE POOL	LINK SOURCE				
SET UP					
INPUT 1	PE-0102e	20272.98 LITERS @	104.00 HOURS, TRANSFER IN	0.0 HOURS=	0.0 LPM
INPUT 2		0 LITERS @	0.00 HOURS, TRANSFER IN	0.0 HOURS=	0.0 LPM
INPUT 3		0 LITERS @	0.00 HOURS, TRANSFER IN	0.0 HOURS=	0.0 LPM
INPUT 4		0 LITERS @	0.00 HOURS, TRANSFER IN	0.0 HOURS=	0.0 LPM
INPUT 5		0 LITERS @	0.00 HOURS, TRANSFER IN	0.0 HOURS=	0.0 LPM
INPUT 6		0 LITERS @	0.00 HOURS, TRANSFER IN	0.0 HOURS=	0.0 LPM
POOL INPUTS		20272.98 LITERS IN	0.00 HOURS, TRANSFER IN	0.0 HOURS=	0.0 LPM
SUB TOTAL			104.00 TOTAL TRANSFER	0 HOURS	LPM MISC.
2.1.1.1 51 OUTLET HEAT EXCHANGE					
SET UP					
TRANSFER	20,273.0 L IN	2.50 HRS =	135.2 LPM		
WASH					
CIP					
SIP					
CLEAN UP					
SUB TOTAL			135.2		
3.1.1.1 26 CONT. CERT/SOLIDS					
SET UP					
CENTRIFUGATION	20,273.0 L IN	5.00 HRS =	56.3 LPM		
WASH	30.0 L IN	0.01 HRS =	56.3 LPM		
CIP					
SIP					
CLEAN UP					
SUB TOTAL			56.3 LPM		
4.1.1.1 48 RESOLUBILIZATION					
SET UP					
DILUTION	6,476.0 L IN	3.0 HOURS	38.0 LPM		
MO		0.0 HOURS			
CIP					
SIP					
CLEAN UP					
SUB TOTAL			36.0		
5.1.1.1 61 INLET HEAT EXCHANGE					
SET UP					
TRANSFER	8,634.7 L IN	2.5 HRS =	57.56 LPM		
WASH	0.0 L IN	0.0 HRS =	0.0 LPM		

2302

2304

FIG.23A-1

Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

PROCESS TIME LINE

DURATION (HRS)			REL. TIME SCALE (HRS)			ABS. HOURS		ABS. DAYS		START		FINISH	
CALC.	LOG	ADJ.	PREP	EXEC.	COMPL.	START	END	START	END	DATE	TIME	DATE	TIME
0.0	0.0	0.0 HRS	104.0			104.0	104.0	4.33	4.33	01/08/99	06:00 AM	01/08/99	08:00 AM
0.0	0.0	0.0 HRS		104.0		104.0	104.0	4.33	4.33	01/08/99	06:00 AM	01/08/99	08:00 AM
0.0	0.0	0.0 HRS				0.0	0.0	0.00	0.00				
0.0	0.0	0.0 HRS				0.0	0.0	0.00	0.00				
0.0	0.0	0.0 HRS				0.0	0.0	0.00	0.00				
0.0	0.0	0.0 HRS				0.0	0.0	0.00	0.00				
0.0	0.0	0.0 HRS				0.0	0.0	0.00	0.00				
0.0	0.0	0.0 HRS				0.0	0.0	0.00	0.00				
0.0	0.0	0.0 HRS				0.0	0.0	0.00	0.00				
0.0	0.0	0.0 HRS		104.0		104.0	104.0	4.33	4.33	01/08/99	06:00 AM	01/08/99	08:00 AM
0.0		0.0 HRS		104.0			0.0			01/08/99	06:00 AM	01/08/99	08:00 AM
										HRS/CY	0.0		
										OK			
1.0	0.0	1.0 HRS	104.0			103.0	104.0	4.28	4.33	01/08/99	07:00 AM	01/08/99	08:00 AM
2.50	0.0	2.5 HRS		106.5		104.0	105.5	4.33	4.44	01/08/99	08:00 AM	01/08/99	10:30 AM
0.63	0.0	0.5 HRS		107.1		106.5	107.1	4.44	4.46	01/08/99	10:30 AM	01/08/99	11:07 AM
0.0	0.0	0.0 HRS			107.1	107.1	107.1	4.46	4.46	01/08/99	11:07 AM	01/08/99	11:07 AM
0.0	0.0	0.0 HRS			107.1	107.1	107.1	4.46	4.46	01/08/99	11:07 AM	01/08/99	11:07 AM
2.0	0.0	2.0 HRS			109.1	107.1	109.1	4.46	4.55	01/08/99	11:07 AM	01/08/99	01:07 PM
5.1		5.1 HRS		106.5						01/08/99	07:00 AM	01/08/99	01:07 PM
										HRS/CY	5.1		
										OK			
1.0	0.0	1.0 HRS	105.6			105.6	106.5	4.00	4.44	01/08/99	09:30 AM	01/08/99	10:30 AM
6.0	0.0	6.0 HRS		112.5		106.5	112.5	4.64	4.64	01/08/99	10:30 AM	01/08/99	04:30 PM
0.0	0.0	0.0 HRS		112.5		112.5	112.5	4.68	4.68	01/08/99	04:10 PM	01/08/99	04:30 PM
0.0	0.0	0.0 HRS			112.5	112.5	112.5	4.68	4.68	01/08/99	04:10 PM	01/08/99	04:30 PM
0.0	0.0	0.0 HRS			112.5	112.5	112.5	4.68	4.68	01/08/99	04:30 PM	01/08/99	04:30 PM
0.0	0.0	0.0 HRS			112.5	112.5	112.5	4.68	4.68	01/08/99	04:30 PM	01/08/99	04:30 PM
7.0		7.0 HRS		112.5			112.5			01/08/99	09:30 AM	01/08/99	04:30 PM
										HRS/CY	3.0		
										OK			
1.0	0.0	1.0 HRS	112.6			111.0	112.0	4.85	4.68	01/08/99	03:30 PM	01/08/99	04:30 PM
3.00	0.0	3.0 HRS		115.5		112.5	115.5	4.88	4.81	01/08/99	04:30 PM	01/08/99	07:30 PM
0.00	0.0	0.0 HRS		115.5		115.5	115.5	4.81	4.81	01/08/99	07:30 PM	01/08/99	07:30 PM
0.0	0.0	0.0 HRS			115.5	115.5	115.5	4.81	4.81	01/08/99	07:30 PM	01/08/99	07:30 PM
0.00	0.0	0.0 HRS			115.5	115.5	115.5	4.81	4.81	01/08/99	07:30 PM	01/08/99	07:30 PM
1.00	0.0	1.0 HRS			116.5	115.5	118.5	4.81	4.85	01/08/99	07:30 PM	01/08/99	08:30 PM
5.00		5.00 HRS		115.5						01/08/99	03:30 PM	01/08/99	08:30 PM
										HRS/CY	5.0		
										OK			
1.0	0.0	1.0 HRS	115.5			114.5	115.5	4.77	4.81	01/08/99	06:30 PM	01/08/99	07:30 PM
2.50	0.0	2.5 HRS		118.0		115.5	118.0	4.81	4.92	01/08/99	07:30 PM	01/08/99	10:00 PM
0.00	0.0	0.0 HRS		118.0		118.0	118.0	4.92	4.92	01/08/99	10:00 PM	01/08/99	10:00 PM

2306 2308 2310 2312 2314 2316 2318 2320 2322 2324 2326 2328 2330

FIG. 23A-2

Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

OPERATION	CALCULATIONS			
CIP SIP CLEAN UP				
SUB TOTAL			57.6	
6.1.1.1 31 HOMMOGENIZATION SET UP LYCIS WASH CIP SIP CLEAN UP	3834.7 L IN 0.0 L IN	2.5 HRS 0.0 HRS	= =	57.6 LPM 0.0 LPM
SUB TOTAL			57.564344	
7.1.1.1 51 OUTLET HEAT EXCHANGE SET UP TRANSFER WASH CIP SIP CLEAN UP	3543.7 L IN 0.0 L IN	2.5 HRS 0.0 HRS	= =	57.58 LPM 0.0 LPM
SUB TOTAL			57.56	
5.1.2.1 61 INLET HEAT EXCHANGE SET UP TRANSFER WASH CIP SIP CLEAN UP	8634.7 L IN 0.0 L IN	2.5 HRS 0.0 HRS	= =	57.56 LPM 0.0 LPM
SUB TOTAL				
6.1.2.1 31 HOMMOGENIZATION SET UP DILUTION MO CIP SIP CLEAN UP	6834.7 L IN 0.0 L IN	2.5 HRS 0.0 HRS	= =	57.6 LPM 0.0 LPM
SUB TOTAL			57.56	
7.1.2.1 51 OUTLET HEAT EXCHANGE				

FIG.23B-1

Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

PROCESS TIME LINE													
DURATION (HRS)			REL. TIME SCALE (HRS)			ABS. HOURS		ABS. DAYS		START		FINISH	
CALC.	LOG	ADJ.	PREP	EXEC.	COMPL.	START	END	START	END	DATE	TIME	DATE	TIME
0.0	0.0	0.0 HRS			118.0	118.0	118.0	4.92	4.92	01/08/99	10:00 PM	01/08/99	10:00 PM
0.0	0.0	0.0 HRS			118.0	118.0	118.0	4.92	4.92	01/08/99	10:00 PM	01/08/99	10:00 PM
0.0	0.0	0.0 HRS			118.0	118.0	118.0	4.92	4.92	01/08/99	10:00 PM	01/08/99	10:00 PM
2.5		2.5 HRS		116.0						01/08/99	06:30 PM	01/08/99	10:00 PM
										HRS/CY	3.5		
										OK			
1.0	0.0	1.0 HRS	118.0			117.0	118.0	4.88	4.92	01/08/99	08:00 AM	01/08/99	10:00 PM
2.5	0.0	2.5 HRS		120.5		118.0	120.5	4.92	5.02	01/08/99	10:00 PM	01/08/99	12:30 AM
0.00	0.0	0.0 HRS		120.5		120.5	120.5	5.02	5.02	01/08/99	12:30 AM	01/08/99	12:30 AM
0.0	0.0	0.0 HRS			120.5	120.5	120.5	5.02	5.02	01/08/99	12:30 AM	01/08/99	12:30 AM
0.0	0.0	0.0 HRS			120.5	120.5	120.5	5.02	5.02	01/08/99	12:30 AM	01/08/99	12:30 AM
0.0	0.0	0.0 HRS			120.5	120.5	120.5	5.02	5.02	01/08/99	12:30 AM	01/08/99	12:30 AM
3.5		3.5 HRS		120.5			120.5			01/08/99	09:00 PM	01/08/99	12:30 AM
										HRS/CY	3.5		
										OK			
1.0	0.0	1.0 HRS	120.5			118.5	120.0	4.88	5.02	01/08/99	11:30 PM	01/08/99	12:30 AM
2.50	0.0	2.5 HRS		123.0		120.5	123.0	5.02	5.13	01/08/99	12:30 AM	01/08/99	03:00 AM
0.00	0.0	0.0 HRS		123.0		123.0	123.0	5.13	5.13	01/08/99	03:00 AM	01/08/99	03:00 AM
0.0	0.0	0.0 HRS			123.0	123.0	123.0	5.13	5.13	01/08/99	03:00 AM	01/08/99	03:00 AM
0.0	0.0	0.0 HRS			123.0	123.0	123.0	5.13	5.13	01/08/99	03:00 AM	01/08/99	03:00 AM
0.0	0.0	0.0 HRS			123.0	123.0	123.0	5.13	5.13	01/08/99	03:00 AM	01/08/99	03:00 AM
2.5		2.5 HRS		123.0						01/08/99	11:30 PM	01/08/99	03:00 AM
										HRS/CY	3.5		
										OK			
0.0	0.0	0.0 HRS	123.0			123.0	123.0	5.13	5.13	01/08/99	03:00 AM	01/08/99	03:00 AM
2.50	0.0	2.5 HRS		125.5		123.0	125.5	5.13	5.23	01/08/99	03:00 AM	01/08/99	05:30 AM
0.00	0.0	0.0 HRS		125.5		125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
0.0	0.0	0.0 HRS			125.5	125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
0.0	0.0	0.0 HRS			125.5	125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
0.0	0.0	0.0 HRS			125.5	125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
2.5		2.5 HRS		125.5 Q1F895						01/08/99	03:00 AM	01/08/99	05:30 AM
										HRS/CY	2.5		
										OK			
1.0	0.0	0.0 HRS	123.0			123.0	123.0	5.13	5.13	01/08/99	03:00 AM	01/08/99	03:00 AM
2.5	0.0	2.5 HRS		125.5		123.0	125.5	5.13	5.23	01/08/99	03:00 AM	01/08/99	05:30 AM
0.00	0.0	0.0 HRS		125.5		125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
0.0	0.0	0.0 HRS			125.5	125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
0.0	0.0	0.0 HRS			125.5	125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
0.0	0.0	0.0 HRS			125.5	125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
2.5		2.5 HRS		125.5			125.5			01/08/99	03:00 AM	01/08/99	05:30 AM
										HRS/CY	2.5		
										OK			

FIG.23B-2

Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

OPERATION	CALCULATIONS			
SET UP				
TRANSFER	8543.7 L IN	2.5 HRS	=	57.56 LPM
WASH	0.0 L IN	0.0 HRS	=	0.0 LPM
CIP				
SIP				
CLEAN UP				
SUB TOTAL				
5.1.3.1 61 INLET HEAT EXCHANGE				
SET UP				
TRANSFER	8634.7 L IN	2.5 HRS	=	57.58 LPM
WASH	9.0 L IN	0.0 HRS	=	57.6 LPM
CIP				
SIP				
CLEAN UP				
SUB TOTAL				
6.1.3.1 31 HOMMOGENIZATION				
SET UP				
LYCIS	8634.7 L IN	2.5 HRS	=	57.6 LPM
WASH	9.0 L IN	0.0 HRS	=	57.6 LPM
CIP				
SIP				
CLEAN UP				
SUB TOTAL				57.56 LPM
7.1.3.1 51 OUTLET HEAT EXCHANGE				
SET UP				
TRANSFER	8643.7 L IN	2.5 HRS	=	57.50 LPM
WASH	9.0 L IN	0.0 HRS	=	57.6 LPM
CIP				
SIP				
CLEAN UP				
SUB TOTAL				

FIG.23C-1

Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

PROCESS TIME LINE

DURATION (HRS)			REL. TIME SCALE (HRS)			ABS. HOURS		ABS. DAYS		START		FINISH	
CALC.	LOG	ADJ.	PREP	EXEC.	COMPL.	START	END	START	END	DATE	TIME	DATE	TIME
0.0	0.0	0.0 HRS	123.0			123.0	123.0	5.13	5.13	01/08/99	03:00 AM	01/08/99	03:00 AM
2.50	0.0	2.5 HRS		125.5		123.0	125.5	5.13	5.23	01/08/99	03:00 AM	01/08/99	05:30 AM
0.00	0.0	0.0 HRS		125.5		125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
0.0	0.0	0.0 HRS			125.5	125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
0.0	0.0	0.0 HRS			125.5	125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
0.0	0.0	0.0 HRS			125.5	125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
2.5		2.5 HRS		125.5						01/08/99	03:00 AM	01/08/99	05:30 AM
										HRS/CY	2.5		
										OK			
0.0	0.0	0.0 HRS	125.5			125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
2.50	0.0	2.5 HRS		128.0		125.5	128.0	5.33	5.33	01/08/99	05:30 AM	01/08/99	08:00 AM
0.0	0.0	0.0 HRS		128.0		128.0	128.0	5.33	5.33	01/08/99	08:00 AM	01/08/99	08:01 AM
0.0	0.0	0.0 HRS			128.0	128.0	128.0	5.33	5.33	01/08/99	08:01 AM	01/08/99	08:01 AM
0.0	0.0	0.0 HRS			128.0	128.0	128.0	5.33	5.33	01/08/99	08:01 AM	01/08/99	08:01 AM
0.0	0.0	0.0 HRS			128.0	128.0	128.0	5.33	5.33	01/08/99	08:01 AM	01/08/99	08:01 AM
2.5		2.5 HRS		128.0						01/08/99	05:30 AM	01/08/99	08:01 AM
										HRS/CY	2.5		
										OK			
0.0	0.0	0.0 HRS	125.5			125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
2.5	0.0	2.5 HRS		128.0		125.5	128.0	5.23	5.33	01/08/99	05:30 AM	01/08/99	08:00 AM
0.0	0.0	0.0 HRS		128.0		128.0	128.0	5.33	5.33	01/08/99	08:00 AM	01/08/99	08:01 AM
0.0	0.0	0.0 HRS			128.0	128.0	128.0	5.33	5.33	01/08/99	08:01 AM	01/08/99	08:01 AM
0.0	0.0	0.0 HRS			128.0	128.0	128.0	5.33	5.33	01/08/99	08:01 AM	01/08/99	08:01 AM
0.0	0.0	0.0 HRS			128.0	128.0	128.0	5.33	5.33	01/08/99	08:01 AM	01/08/99	08:01 AM
2.5		2.5 HRS		128.0			128.0			01/08/99	05:30 AM	01/08/99	08:01 AM
										HRS/CY	2.5		
										OK			
0.0	0.0	0.0 HRS	125.5			125.5	125.5	5.23	5.23	01/08/99	05:30 AM	01/08/99	05:30 AM
2.50	0.0	2.5 HRS		128.0		125.5	128.0	5.23	5.33	01/08/99	05:30 AM	01/08/99	08:01 AM
0.0	0.0	0.0 HRS		128.0		128.0	128.0	5.33	5.33	01/08/99	08:01 AM	01/08/99	08:01 AM
0.0	0.0	0.0 HRS			128.0	128.0	128.0	5.33	5.33	01/08/99	08:01 AM	01/08/99	08:01 AM
0.0	0.0	0.0 HRS			128.0	128.0	128.0	5.33	5.33	01/08/99	08:01 AM	01/08/99	08:01 AM
0.0	0.0	0.0 HRS			128.0	128.0	128.0	5.33	5.33	01/08/99	08:01 AM	01/08/99	08:01 AM
2.5		2.5 HRS		128.0			128.0			01/08/99	05:30 AM	01/08/99	08:01 AM
										HRS/CY	2.5		
										OK			

FIG.23C-2

Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

	FIRST SHIFT				SECOND SHIFT			
	START	07:00 AM	FINISH	03:00 PM	START	03:00 PM	FINISH	11:00 PM
OPERATION	DATE	TIME	DATE	TIME	DATE	TIME	DATE	TIME
1.1.1.1 T76 MUTI-STAGE POOL	01/08/99	08:00 AM	01/08/99	08:00 AM				
	01/08/99	08:00 AM	01/08/99	08:00 AM				
SET UP								
INPUT 1								
INPUT 2								
INPUT 3								
INPUT 4								
INPUT 5								
INPUT 6								
POOL INPUTS	01/08/99	08:00 AM	01/08/99	08:00 AM				
SUB TOTAL								
2.1.1.1 51 OUTLET HEAT EXCHANGE								
SET UP			01/08/99	08:00 AM				
TRANSFER	01/08/99	08:00 AM	01/08/99	10:30 AM				
WASH	01/08/99	10:30 AM	01/08/99	11:07 AM				
CIP	01/08/99	11:07 AM	01/08/99	11:07 AM				
SIP	01/08/99	11:07 AM	01/08/99	11:07 AM				
CLEAN UP	01/08/99	11:07 AM	01/08/99	01:07 PM				
SUB TOTAL								
3.1.1.1 26 CONT. CERT/SOLIDS								
SET UP	01/08/99	09:30 AM	01/08/99	10:30 AM			01/08/99	04:30 PM
CENTRIFUGATION	01/08/99	10:30 AM			01/08/99	04:30 PM	01/08/99	04:30 PM
WASH					01/08/99	04:30 PM	01/08/99	04:30 PM
CIP					01/08/99	04:30 PM	01/08/99	04:30 PM
SIP					01/08/99	04:30 PM	01/08/99	04:30 PM
CLEAN UP					01/08/99	04:30 PM	01/08/99	04:30 PM
SUB TOTAL								
4.1.1.1 48 RESOLUBILIZATION								
SET UP					01/08/99	03:30 PM	01/08/99	04:30 PM
DILUTION					01/08/99	04:30 PM	01/08/99	07:30 PM
MO					01/08/99	07:30 PM	01/08/99	07:30 PM
CIP					01/08/99	07:30 PM	01/08/99	07:30 PM
SIP					01/08/99	07:30 PM	01/08/99	07:30 PM
CLEAN UP					01/08/99	07:30 PM	01/08/99	08:30 PM
SUB TOTAL								
5.1.1.1 61 INLET HEAT EXCHANGE								
SET UP					01/08/99	06:30 PM	01/08/99	07:30 PM
TRANSFER					01/08/99	07:30 PM	01/08/99	10:00 PM
WASH					01/08/99	10:00 PM	01/08/99	10:00 PM

FIG.23D-1

Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

THIRD SHIFT			
START	11:04 PM	FINISH	04:07 AM
DATE	TIME	DATE	TIME
01/08/99	07:00 AM		

FIG.23D-2

Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

	FIRST SHIFT				SECOND SHIFT			
	START	07:00 AM	FINISH	03:00 PM	START	01:00 PM	FINISH	11:00 PM
OPERATION	DATE	TIME	DATE	TIME	DATE	TIME	DATE	TIME
CIP					01/08/99	10:00 PM	01/08/99	10:00 PM
SIP					01/08/99	10:00 PM	01/08/99	10:00 PM
CLEAN UP					01/08/99	10:00 PM	01/08/99	10:00 PM
SUB TOTAL								
6.1.1.1 31 HOMMOGENIZATION								
SET UP					01/08/99	09:00 PM	01/08/99	10:00 PM
LYCIS					01/08/99	10:00 PM		
WASH								
CIP								
SIP								
CLEAN UP								
SUB TOTAL								
7.1.1.1 51 OUTLET HEAT EXCHANGE								
SET UP								
TRANSFER								
WASH								
CIP								
SIP								
CLEAN UP								
SUB TOTAL								
5.1.2.1 61 INLET HEAT EXCHANGE								
SET UP								
TRANSFER								
WASH								
CIP								
SIP								
CLEAN UP								
SUB TOTAL								
6.1.2.1 31 HOMMOGENIZATION								
SET UP								
LYCIS								
WASH								
CIP								
SIP								
CLEAN UP								
SUB TOTAL								
7.1.2.1 51 OUTLET HEAT EXCHANGE								

FIG.23E-1

Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

THIRD SHIFT			
START	11:00 PM	FINISH	08:00 AM
DATE	TIME	DATE	TIME
		01/08/99	12:30 AM
01/08/99	12:30 AM	01/08/99	12:30 AM
01/08/99	12:30 AM	01/08/99	12:30 AM
01/08/99	11:30 PM	01/08/99	12:30 AM
01/08/99	12:30 AM	01/08/99	03:00 AM
01/08/99	03:00 AM	01/08/99	03:00 AM
01/08/99	03:00 AM	01/08/99	03:00 AM
01/08/99	03:00 AM	01/08/99	03:00 AM
01/08/99	03:00 AM	01/08/99	03:00 AM
01/08/99	03:00 AM	01/08/99	03:00 AM
01/08/99	03:00 AM	01/08/99	05:30 AM
01/08/99	05:30 AM	01/08/99	05:30 AM
01/08/99	05:30 AM	01/08/99	05:30 AM
01/08/99	05:30 AM	01/08/99	05:30 AM
01/08/99	05:30 AM	01/08/99	05:30 AM
01/08/99	03:00 AM	01/08/99	03:00 AM
01/08/99	03:00 AM	01/08/99	05:30 AM
01/08/99	05:30 AM	01/08/99	05:30 AM
01/08/99	05:30 AM	01/08/99	05:30 AM
01/08/99	05:30 AM	01/08/99	05:30 AM
01/08/99	05:30 AM	01/08/99	05:30 AM

FIG.23E-2

Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

		FIRST SHIFT				SECOND SHIFT			
		START	07:00 AM	FINISH	03:00 PM	START	03:00 PM	FINISH	11:00 PM
	OPERATION	DATE	TIME	DATE	TIME	DATE	TIME	DATE	TIME
	SET UP								
	TRANSFER								
	WASH								
	CIP								
	SIP								
	CLEAN UP								
	SUB TOTAL								
5.1.3.1 61	INLET HEAT EXCHANGE								
	SET UP								
	TRANSFER			01/08/99	08:00 AM				
	WASH	01/08/99	08:00 AM	01/08/99	08:01 AM				
	CIP	01/08/99	08:01 AM	01/08/99	08:01 AM				
	SIP	01/08/99	08:01 AM	01/08/99	08:01 AM				
	CLEAN UP	01/08/99	08:01 AM	01/08/99	08:01 AM				
	SUB TOTAL								
6.1.3.1 31	HOMMOGENIZATION								
	SET UP								
	LYCIS			01/08/99	08:00 AM				
	WASH	01/08/99	08:00 AM	01/08/99	08:01 AM				
	CIP	01/08/99	08:01 AM	01/08/99	08:01 AM				
	SIP	01/08/99	08:01 AM	01/08/99	08:01 AM				
	CLEAN UP	01/08/99	08:01 AM	01/08/99	08:01 AM				
	SUB TOTAL								
7.1.3.1 51	OUTLET HEAT EXCHANGE								
	SET UP								
	TRANSFER			01/08/99	08:01 AM				
	WASH	01/08/99	08:01 AM	01/08/99	08:01 AM				
	CIP	01/08/99	08:01 AM	01/08/99	08:01 AM				
	SIP	01/08/99	08:01 AM	01/08/99	08:01 AM				
	CLEAN UP	01/08/99	08:01 AM	01/08/99	08:01 AM				
	SUB TOTAL								

FIG.23F-1

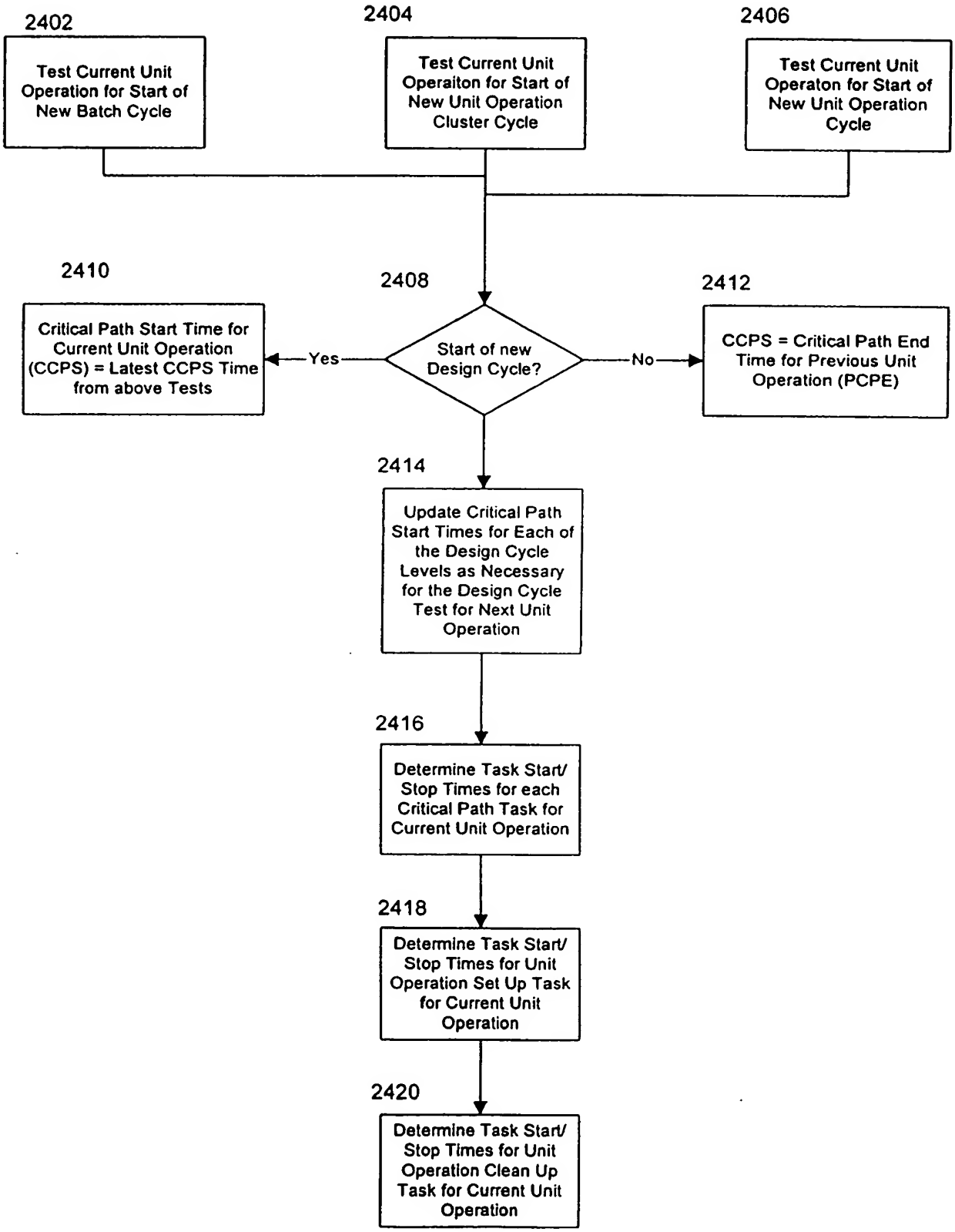
Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

THIRD SHIFT			
START	11:00 PM	FINISH	05:30 AM
DATE	TIME	DATE	TIME
01/08/99	03:00 AM	01/08/99	03:00 AM
01/08/99	03:00 AM	01/08/99	05:30 AM
01/08/99	05:30 AM	01/08/99	05:30 AM
01/08/99	05:30 AM	01/08/99	05:30 AM
01/08/99	05:30 AM	01/08/99	05:30 AM
01/08/99	05:30 AM	01/08/99	05:30 AM
01/08/99	05:30 AM	01/08/99	05:30 AM
01/08/99	05:30 AM		
01/08/99	05:30 AM	01/08/99	05:30 AM
01/08/99	05:30 AM		
01/08/99	05:30 AM	01/08/99	05:30 AM
01/08/99	05:30 AM		

FIG.23F-2

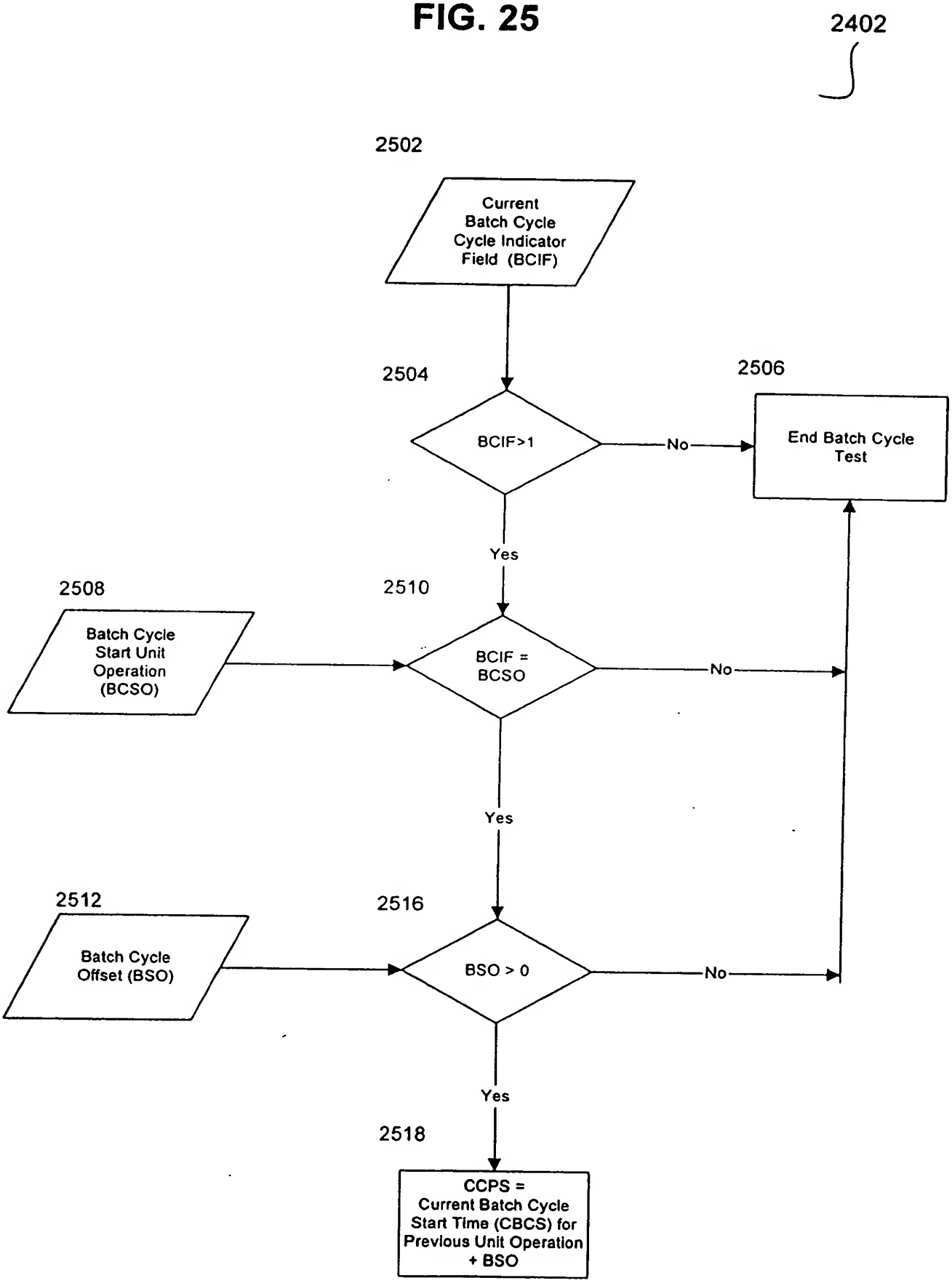
Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

FIG. 24



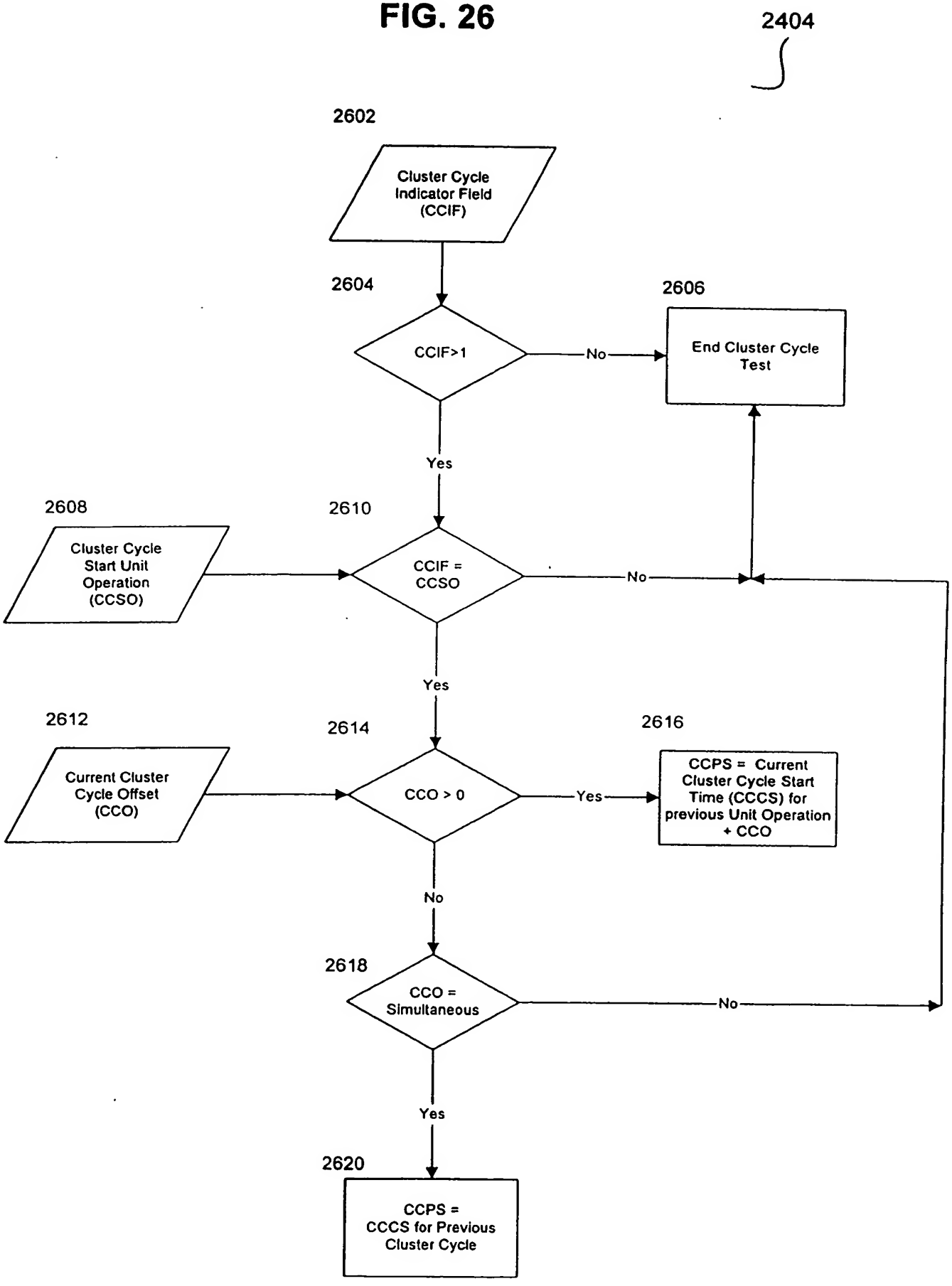
Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

FIG. 25



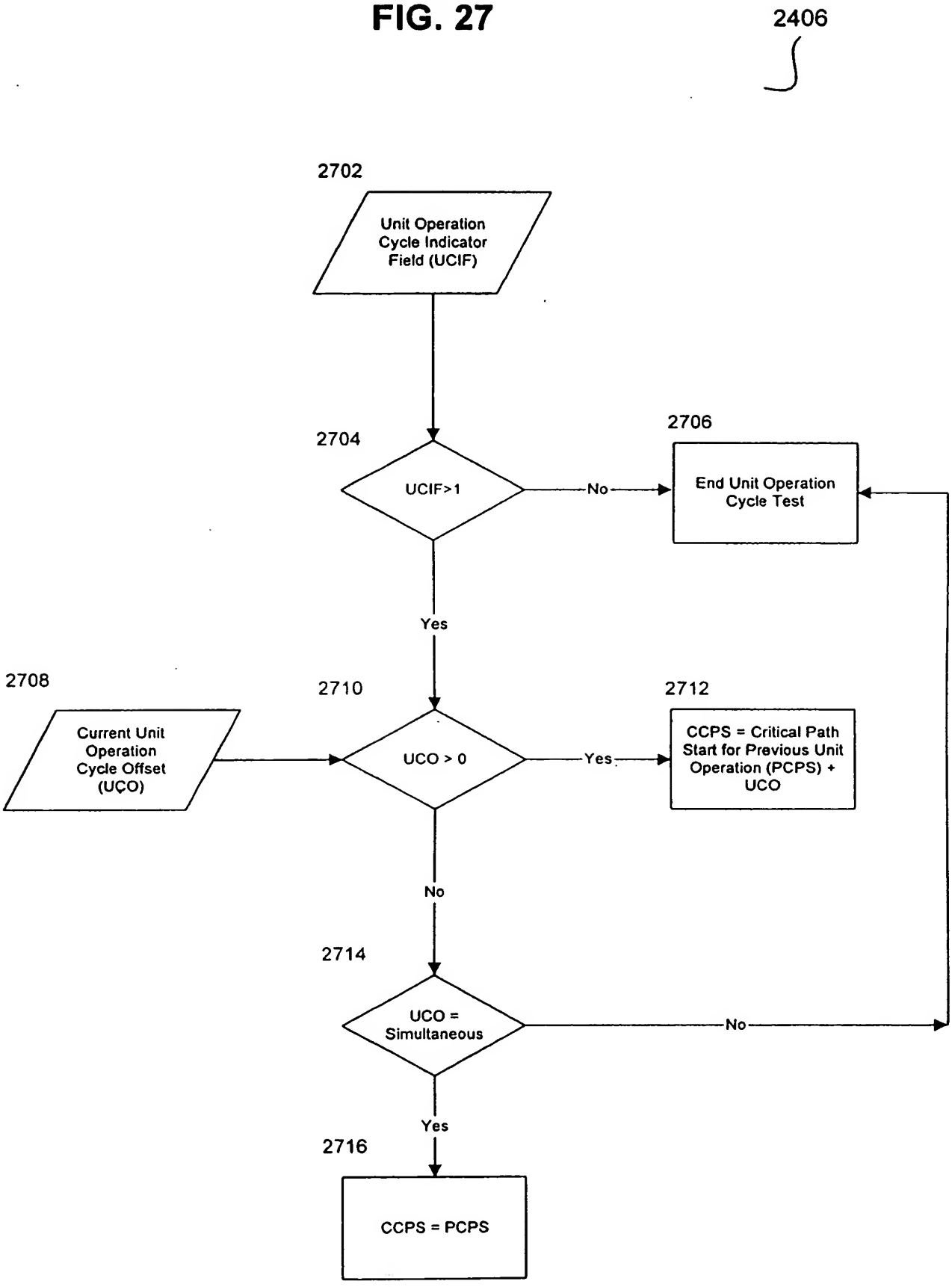
Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

FIG. 26



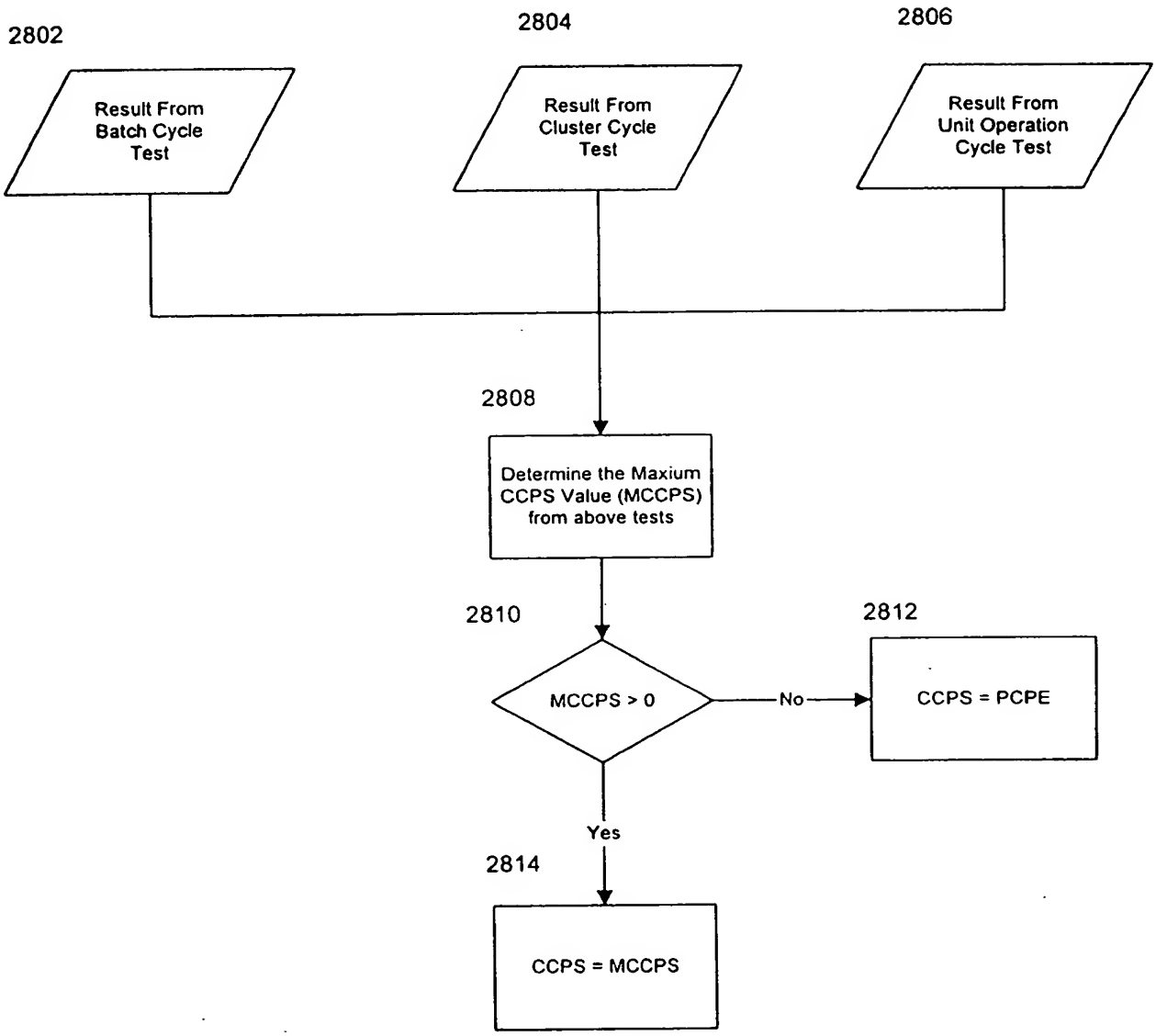
Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

FIG. 27



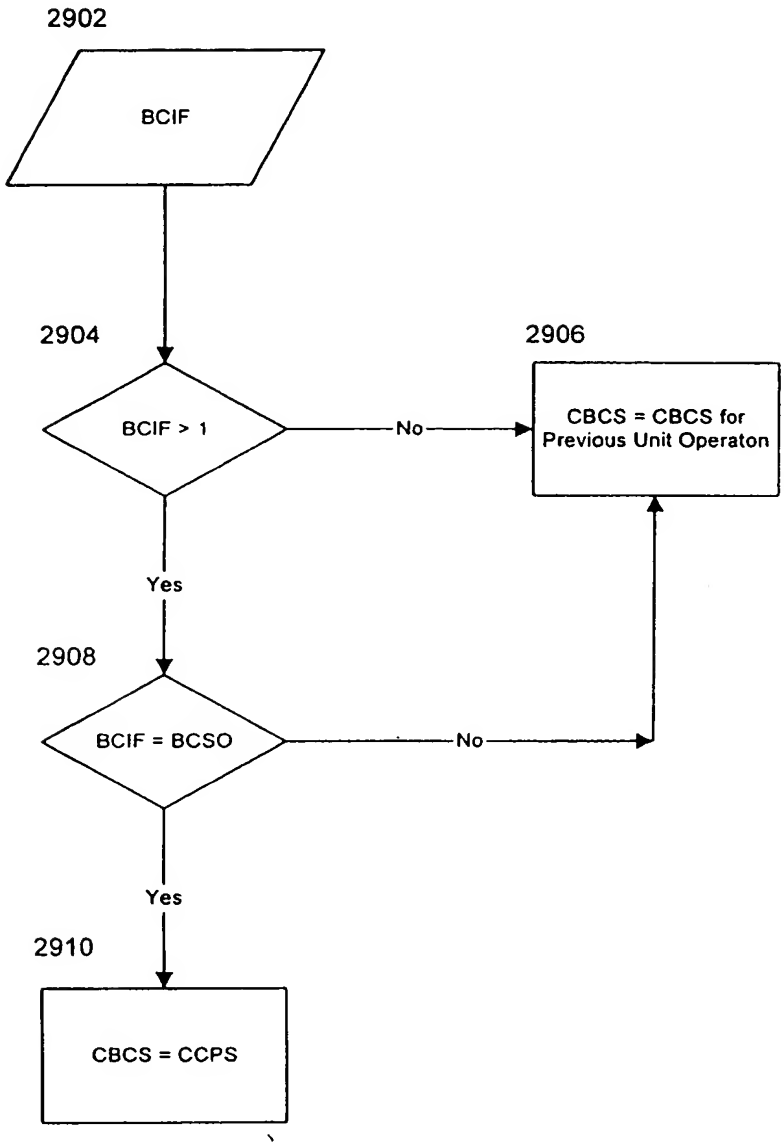
Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

FIG. 28



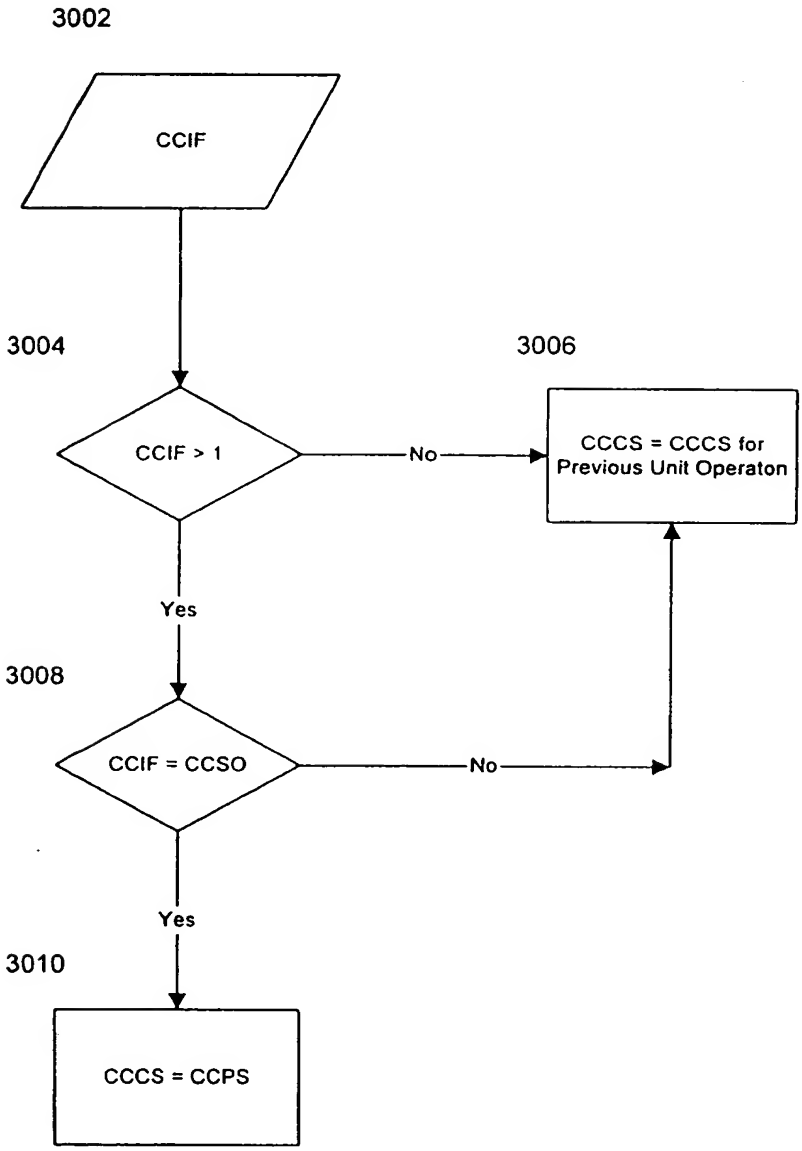
Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

FIG. 29



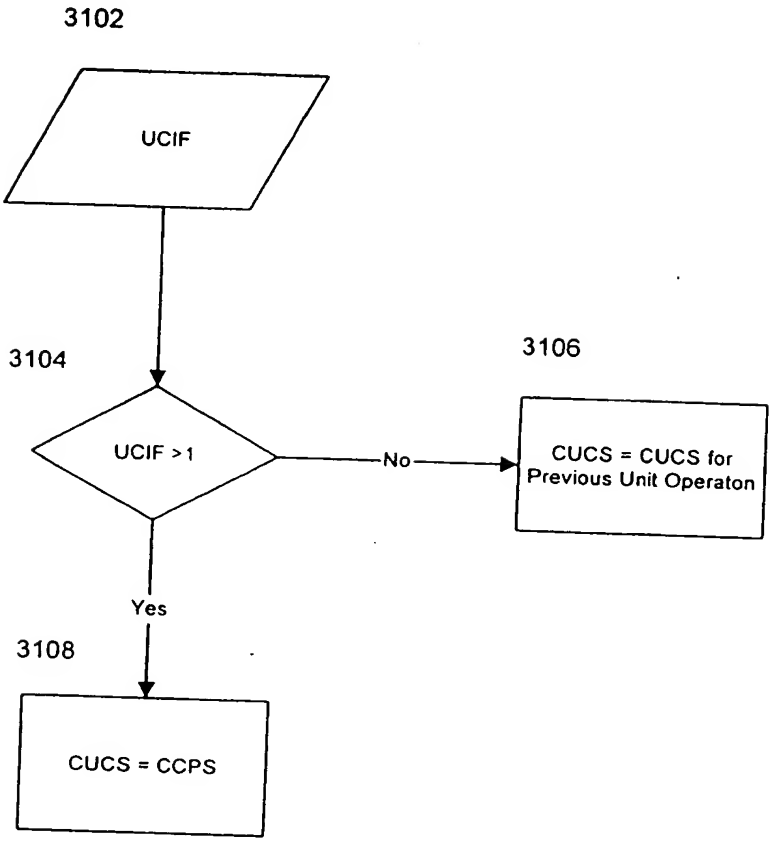
Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

FIG. 30



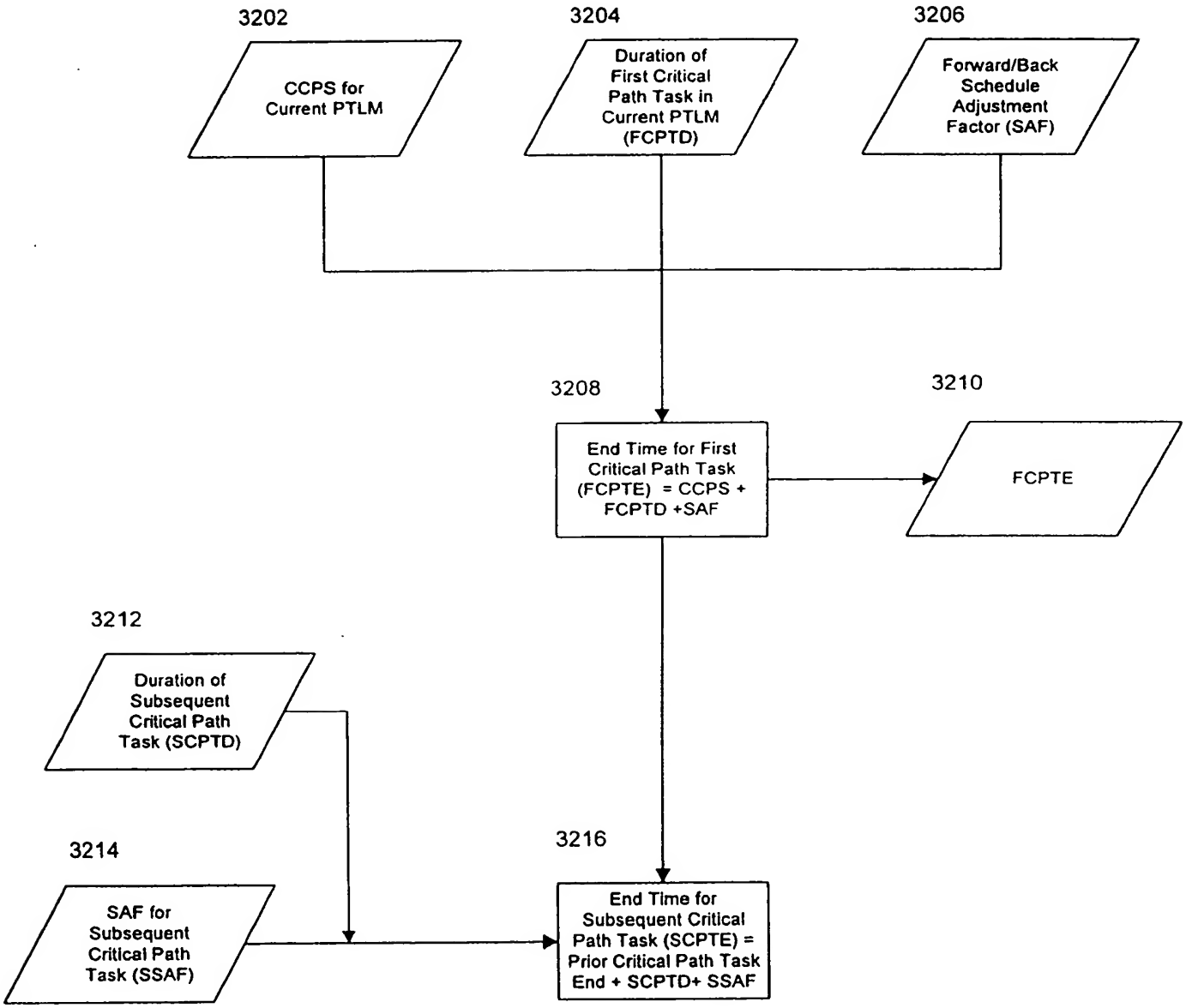
Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

FIG. 31



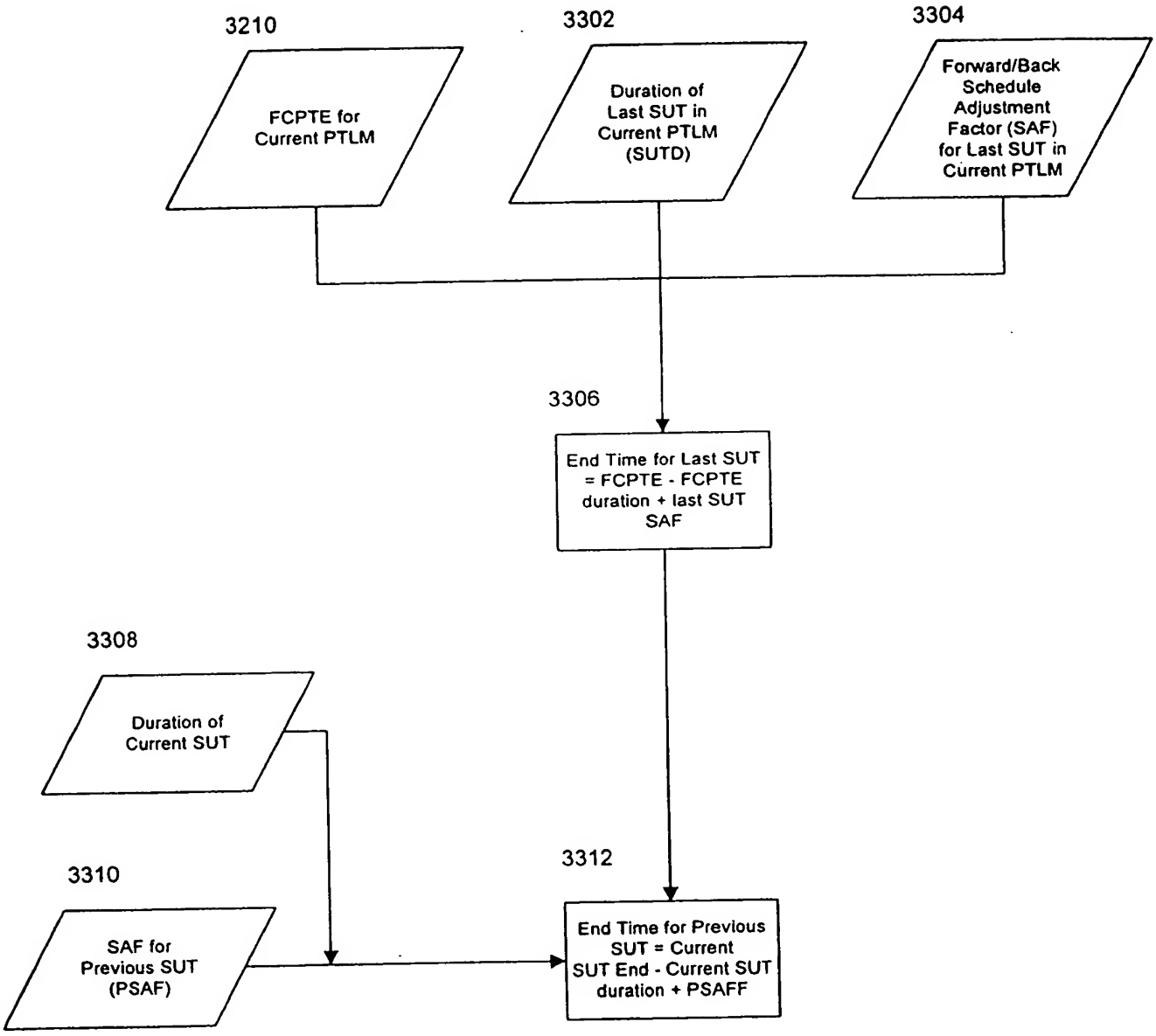
Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

FIG. 32



Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

FIG. 33



Appl. No. To Be Assigned; Filed: HEREWITH
Dkt. No. 1606.0010003; Group Art Unit: TBA
Inventor(s): Peter G. BROWN; Tel: 202/371-2600
Title: System And Method For Simulation And Modeling...

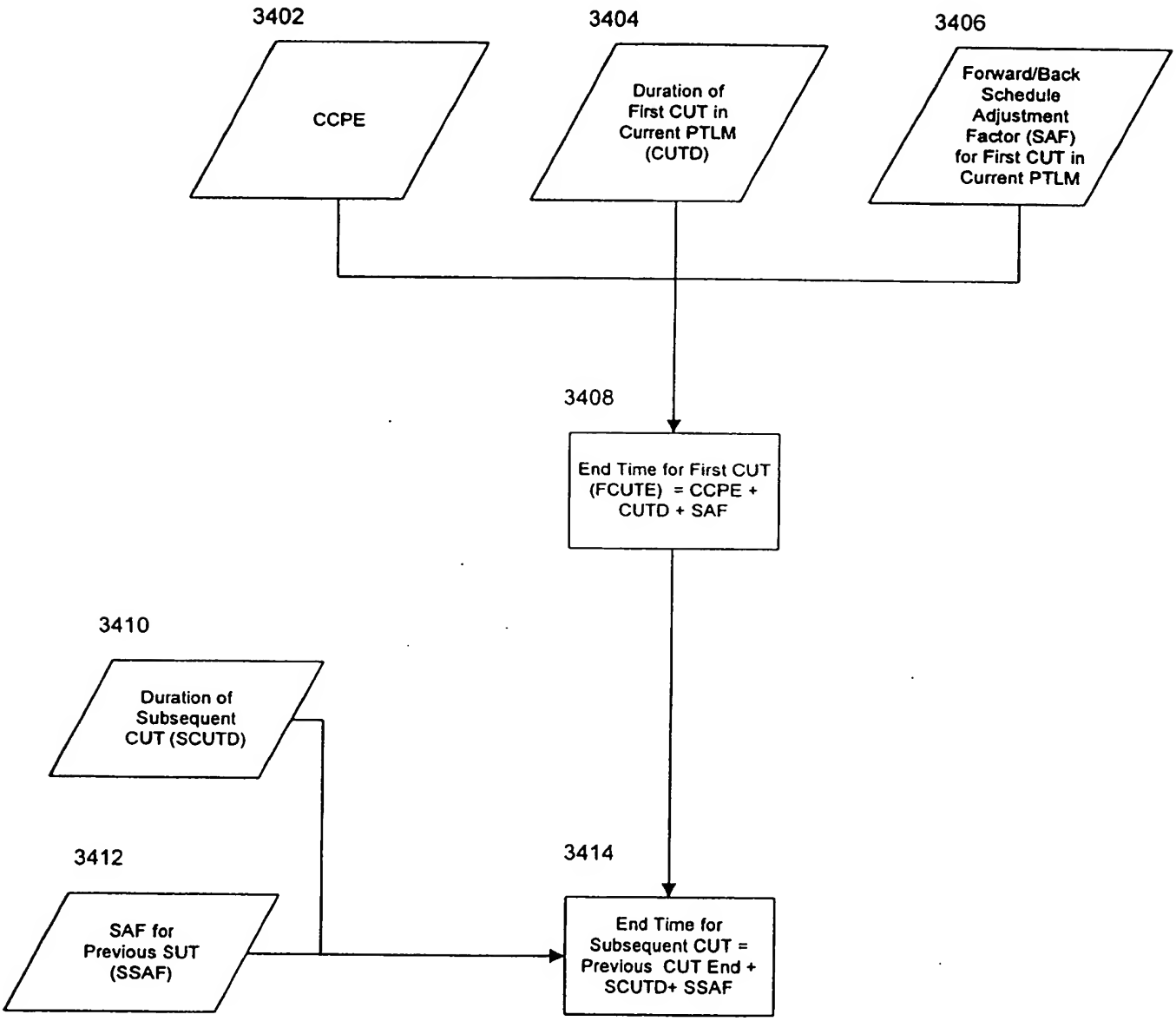



FIG. 34